UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Dr. Russell P. Schneider
Senior Director, Regulatory Affairs and Policy
Monsanto Company
1300 I Street, NW, Suite 450 East
Washington, DC 20005

DEC 15 2008

Re: Monsanto Company, MON 89034
EPA Registration No. 524-575
Amendment to Allow for 5% Structured Refuge in the Corn Belt (Non-Cotton Growing Regions) for Corn Borers
Submission dated 06/11/2008

Dear Dr. Schneider:

The amendment referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided that you comply with the following terms and conditions.

1) The subject registration will automatically expire on midnight September 30, 2010.

2) The subject registration will be limited to MON 89034 in field or sweet corn. Further, MON 89034 sweet corn may only be sold directly to processors or through commercial dealers to large growers. MON 89034 sweet corn must not be sold to small roadside or home growers.

3) Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.

4) This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

CONCURRENCES								
SYMBOL ▶	7511P	7511P	7511P					
SURNAME ▶	KAUSCH	Reynolds	Rull					
DATE ▶	12/11/2008	12/11/08	12/15/08					(2)

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* **OFFICIAL FILE COPY**

* U.S. Government Printing Office: 2005 206-899 (mac)

5) Submit the following data in the time frames listed:

OPPTS Guideline/ Study Type	**Required Data**	**Due Date**
Residue Analytical Method – Plants (OPPTS 860.1340)	For event MON 89034 corn, an independent lab validation of the analytical method for the detection of Cry2Ab2 and/or Cry1A.105. You must also agree to provide to the EPA laboratory (Ft. Meade, MD) methodology and/or reagents necessary for validation of such analytical method within 6 months from the date that the Agency requests them.	4/1/2009
Aquatic Invertebrate Acute Toxicity Testing, Freshwater *Daphnids* (OPPTS 885.4240)	A 7-14 day *Daphnia* study as per the 885 Series OPPTS Guidelines needs to be performed. Alternatively, a dietary study of the effects on an aquatic invertebrate, representing the functional group of a leaf shredder in headwater streams, can be performed and submitted in lieu of the *Daphnia* study.	4/1/2009
Insect Resistance Management – Resistance Monitoring	Monsanto must provide additional information on cross-resistance of Cry1A.105 and Cry1Ac (preferably including binding site models and use of resistant colonies) for the target pests and determine how such cross-resistance may impact the durability of MON 89034, including any impacts in the southern cotton-growing areas. The Cry1A.105 protein is a chimeric protein consisting of Domains I and II and the C-terminus of Cry1Ac. It is important to address not only the likelihood of cross-resistance potential of Cry1A.105 and Cry1Ab and, similarly, Cry1A.105 and Cry2Ab2 (which was done by Monsanto) but also that of Cry1A.105 and Cry1Ac.	4/1/2009
Insect Resistance Management – Resistance Monitoring	Baseline susceptibility studies and/or a discriminating concentration assay are required for the Cry1A.105 protein against European corn borer (ECB), Southwestern corn borer (SWCB), and corn earworm (CEW) and for the Cry2Ab2 protein against SWCB and CEW.	4/1/2009

OPPTS Guideline/ Study Type	Required Data	Due Date
Insect Resistance Management – Resistance Monitoring	To support sweet corn uses, baseline susceptibility studies must be conducted on fall armyworm (FAW) populations collected from sweet corn growing areas. Monitoring studies will be conducted on FAW populations collected from sweet corn distribution areas in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 5,000 acres. The collected populations of FAW will be monitored for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins.	4/1/2010

6) The Insect Resistance Management (IRM) terms and conditions for this product are as follows.

The required IRM program for MON 89034 must have the following elements:

- Requirements relating to creation of a non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuge in conjunction with the planting of any acreage of MON 89034 field corn;
- Requirements for Monsanto to prepare and require MON 89034 users to sign "grower agreements," which impose binding contractual obligations on the grower to comply with the refuge requirements;
- Requirements regarding programs to educate growers about IRM requirements;
- Requirements regarding programs to evaluate and promote growers' compliance with IRM requirements;
- Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1A.105 and Cry2Ab2 proteins in the target insects;
- Requirements regarding a "remedial action plan," which contains measures Monsanto would take in the event that any field relevant insect resistance was detected as well as to report on activity under the plan to EPA;
- Submit annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreement results, and the compliance assurance program including the education program on or before January 31st each year, beginning in 2010.

a) Refuge Requirements for MON 89034 Field Corn

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year. Furthermore, these refuge requirements do not apply to commercial hybrid sweet corn.

1) Corn-Belt Refuge Requirements

For MON 89034 field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 5% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.

- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.

- External refuges must be planted within ½ mile.

- When planting the refuge as strips across the field or as perimeter strips, refuges must be at least 4 consecutive rows wide.

- Insecticide treatments for control of ECB, CEW, SWCB, and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

2) Cotton-Growing Area Refuge Requirements

For MON 89034 field corn grown in cotton-growing areas, grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/ product use guide.

- Specifically, growers in these areas must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.

- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.

- External refuges must be planted within ½ mile.

- When planting the refuge as strips across the field or as perimeter strips, refuges must be at least 4 consecutive rows wide.

- Insecticide treatments for control of ECB, CEW, SWCB, and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

- Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex), and Missouri (only the counties of Dunkin, New Madrid, Pemiscot, Scott, and Stoddard).

b) Post-Harvest Requirements for MON 89034 Sweet Corn

Sweet corn is harvested long before field corn. Therefore, if the sweet corn stalks remaining in the field and any insects remaining in the stalks are destroyed shortly after harvest, a refuge is not needed as a part of the IRM program for sweet corn. Growers must adhere to the following types of crop destruction requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Crop destruction must occur no later than 30 days following harvest, but preferably within 14 days.

- The allowed crop destruction methods are: rotary mowing, discing, or plow-down. Crop destruction methods should destroy any surviving resistant insects.

c) Grower Agreements for MON 89034

1) Persons purchasing MON 89034 must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3) Monsanto must integrate this registration into the current system used for their other *Bt* corn PIPS, which is reasonably likely to assure that persons purchasing MON 89034 will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4) Monsanto must continue to use their current grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

5) Monsanto must integrate this registration into a current system, which is reasonably likely to assure that persons purchasing MON 89034 sign grower agreement(s).

6) Monsanto shall maintain records of all MON 89034 grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

7) Beginning on January 31, 2010 and annually thereafter, Monsanto shall provide EPA with a report showing the number of units of MON 89034 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July. Note: The first report shall contain the specified information from the time frame starting with the date of registration and ending July 31, 2009.

8) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

d) IRM Education and Compliance Monitoring Programs for MON 89034

1) Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to MON 89034 users the importance of complying with the IRM program. The program shall include information encouraging MON 89034 users to pursue optional elements of the IRM program relating to refuge configuration and proximity to MON 89034 fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each MON 89034 user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraphs 6a or 6b and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) On January 31, 2010, Monsanto must provide a report to EPA summarizing the activities carried out under the education program for the prior year. Annually thereafter, Monsanto must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Monsanto must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC).

4) Monsanto must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing MON 89034 are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to MON 89034. Monsanto shall coordinate with other *Bt* corn registrants in designing and implementing its compliance assurance program and integrate this registration into the current compliance assurance program used for their other *Bt* corn PIPS. Other required features of the program are described in paragraphs 5 – 15 below.

5) Monsanto must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how they will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Monsanto must use a consistent set of standards for responding to non-compliance. The options shall include withdrawal of the right to purchase Monsanto corn PIP products for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of Monsanto corn PIP products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Monsanto corn PIP products.

6a) MON 89034 Field Corn: The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of MON 89034 field corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the United States.

6b) MON 89034 Sweet Corn: The IRM compliance assurance program shall include an annual survey of all MON 89034 sweet corn customers who purchase 5 or more bags of MON 89034 sweet corn. The survey shall measure the degree of compliance with the IRM program, identify the response rate (e.g., the percent of MON 89034 sweet corn acres covered by the responses), and consider the potential impact of non-response. An independent third party will participate in the design and implementation of the survey. Data and information derived from the annual survey will be audited by an independent third party.

7) The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8) The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9a) MON 89034 Field Corn: Monsanto shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31st of each year, beginning in 2010. Monsanto shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

9b) MON 89034 Sweet Corn: Monsanto shall provide a written summary of the results of the prior year's survey (together with a description of the methodology used and the supporting data) to EPA by January 31st of each year, beginning in 2010. Monsanto shall confer with EPA on changes to the design and content of the survey prior to its implementation.

10) Annually, Monsanto shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs 6a through 8 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Monsanto must confer with the Agency prior to adopting any changes.

11) Monsanto shall conduct an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with growers of MON 89034 to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

12) Monsanto shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach."

13) If a grower, who purchases MON 89034 for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

14) Beginning January 31, 2010 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. Monsanto may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

15) Monsanto and the seed corn dealers for Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

e) Insect Resistance Monitoring and Remedial Action Plan for MON 89034

The Agency is imposing the following conditions for the Cry1A.105 and Cry2Ab2 toxins expressed in MON 89034 :

Monsanto will monitor for resistance to Cry1A.105 and Cry2Ab2 expressed in MON 89034. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing and (2) investigation of reports of less-than expected control of labeled insects. Should field relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

(1) Focused Population Sampling

Monsanto will develop and ensure the implementation of a plan for resistance monitoring for *Spodoptera frugiperda* (fall armyworm or FAW) in counties in which MON 89034 and/or MON 89034 x MON 88017 sweet corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. Monsanto should consult with academic and United States Department of Agriculture (USDA) experts in developing the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31st of the year following that in which MON 89034 and/or MON 89034 x MON 88017 sweet corn acreage exceeds the trigger specified in this requirement (i.e., greater than 5,000 acres in any county in which FAW overwinters). The proposed plan must be implemented the season following the acreage trigger being met. The proposed plan will remain in place until an EPA approved plan can be implemented.

Monsanto shall annually sample and bioassay populations of the key target pests: *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to MON 89034 and/or changes in resistance-allele frequency in response to the use of MON 89034 and, as far as possible, should be consistent across sampling years to enable comparisons with historical data. Each protein in MON 89034 must be tested separately, rather than a mixture of the two proteins, because resistance to one protein could be masked by the activity of the other.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of MON 89034. The Agency shall be consulted prior to the implementation of such modifications.

The registrant will report to the Agency by August 31st of each year, beginning in 2010, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1A.105 and Cry2Ab2 proteins in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31st, beginning in 2010. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.

2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to MON 89034 under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.

3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to taken to evaluate the resistance. These steps may include:

   - determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);
   - estimating the resistance-allele frequency in the original population;
   - determining whether the resistance-allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
   - determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Monsanto will consult with the Agency to develop and implement a case-specific resistance management action plan.

(2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:

Monsanto will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Monsanto will instruct its customers to contact them if such incidents occur. Monsanto will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, CEW, and FAW), Monsanto will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance.*

Suspected resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;

- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to MON 89034 in commercial production fields before responsive measures are undertaken.

If resistance is *suspected,* Monsanto will instruct growers to do the following:

- Use alternative control measures in MON 89034 fields in the affected region to control the target pest during the immediate growing season.
- Destroy MON 89034 crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, Monsanto will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance-allele frequency of ≥ 0.1 in the sampled population.

- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

(3) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is *confirmed* (as defined above), the following steps will be taken by Monsanto:

- EPA will receive notification within 30 days of resistance confirmation;

- Affected customers and extension agents will be notified about confirmed resistance within 30 days;

- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;

- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;

- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;

- Monsanto will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Monsanto will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;

- Notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and

- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year, beginning in 2010, for the duration of the conditional registration.

g) Annual Reporting Requirements for MON 89034

1) Annual Sales: reported and summed by state (county level data available by request), January 31st each year, beginning in 2010;

2) Grower Agreement: number of units of MON 89034 seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year, beginning in 2010;

3) Grower Education: substantive changes to education program completed previous year, January 31st each year, beginning in 2010;

4) Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year, beginning in 2010;

5) Compliance Survey Results: to include annual survey results and plans for the next year; full report January 31st each year, beginning in 2010;

6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2010.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of this product constitutes acceptance of these conditions. If you have any questions contact Jeannine Kausch at 703-347-8920 or by email at: kausch.jeannine@epa.gov.

A stamped copy of the label is enclosed for your records.

Sincerely,

Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure (1):
-Accepted Label

Plant-Incorporated Protectant Label

MON 89034

Lepidopteran-Protected Corn
(OECD Unique Identifier: MON-89Ø34-3)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn.....0.0020-0.0056%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn.....0.0015-0.0055%*

*Percentage (wt/wt) on a dry weight basis whole plant (forage)

KEEP OUT OF REACH OF CHILDREN

Caution

NET CONTENTS_____

EPA Registration No. 524-575

EPA Establishment No. 524-MO-002

ACCEPTED
DEC 15 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 524-575

Monsanto Company
800 North Lindbergh Blvd.
St Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the Technology Use Guide.

MON 89034 can be used to protect corn plants from leaf, stalk, and ear damage caused by corn borers.

This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated

protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

1) Refuge Requirements for MON 89034 Field Corn

In order to minimize the risk of corn borers developing resistance to MON 89034 field corn, an insect resistance management plan must be implemented which includes planting of a structured refuge.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year. Furthermore, these refuge requirements do not apply to commercial hybrid sweet corn.

a) **Corn-Belt/Non-Cotton Growing Area Refuge Requirements**

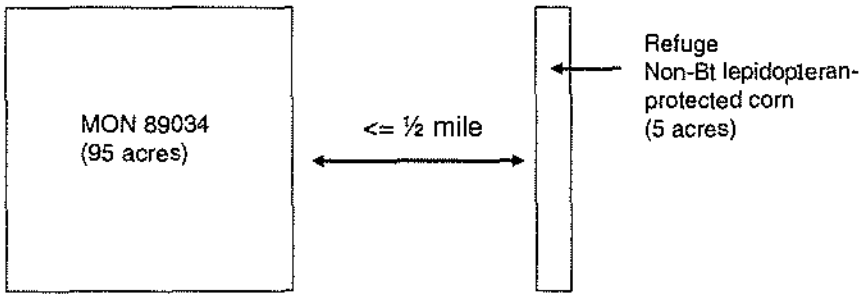
For MON 89034 field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower guides must specify that growers must adhere to the following refuge requirements. Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products.

Growers must plant a structured refuge of at least 5% corn, which is not a lepidopteran-protected Bt corn hybrid. The refuge may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.

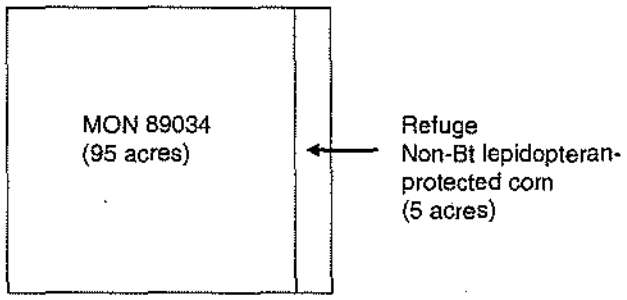
Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, southern cornstalk borer, sugarcane borer, fall armyworm and corn stalk borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial Bt insecticides must not be applied to non-Bt corn refuges.

Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.

External refuges must be planted within ½ mile.



When planting the refuge in strips across the field, refuges must be at least 4 consecutive rows wide.



b) Cotton-Growing Area Refuge Requirements

Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

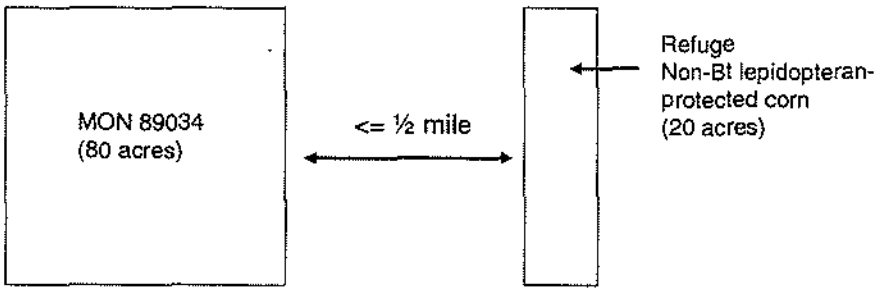
For MON 89034 field corn grown in cotton-growing areas, grower guides must specify that growers must adhere to the following refuge requirements. Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products.

Growers must plant a structured refuge of at least 20% corn which is not a lepidopteran-protected Bt corn hybrid. The refuge may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.

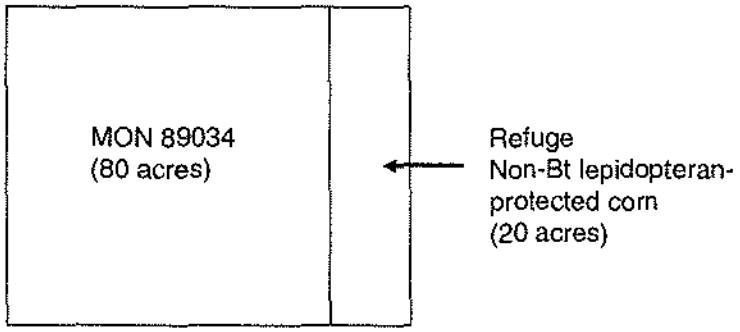
Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, southern cornstalk borer, sugarcane borer, fall armyworm and corn stalk borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial Bt insecticides must not be applied to non-Bt corn refuges.

Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.

External refuges must be planted within ½ mile.



When planting the refuge in strips across the field, refuges must be at least 4 consecutive rows wide.



2) Post-Harvest Requirements for MON 89034 Sweet Corn

For MON 89034 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, discing, or plow-down within one (1) month of harvest.

Corn Insects Controlled

European corn borer	*Ostrinia nubilalis*
Southwestern corn borer	*Diatraea grandiosella*
Southern cornstalk borer	*Diatraea crambidoides*
Corn earworm	*Helicoverpa zea*
Fall armyworm	*Spodoptera frugiperda*
Corn stalk borer	*Papaipema nebris*
Sugarcane borer	*Diatraea saccharalis*

Sales of corn hybrids that contain Monsanto's Bt corn plant incorporated protectant must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to

control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 6018100, 6051753, 6331665, 6489542, 6645497, 6962705, 7064249, and 7250501.

"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>

12/12/2008 09:35 AM

To Jeannine Kausch/DC/USEPA/US@EPA

cc

bcc

Subject RE: MON 89034 and MON 89034 x MON 88017 - Draft acceptance letters going up for signature/labels

History: This message has been replied to.

Jeannine,

We have reviewed the conditions of registration for MON 89034 and MON 89034 X MON 88017 and find them acceptable. Please find attached the final proposed labels for both products.

My sincere thanks,

Russ

Label MON 89034 x MON 88017 Dec 2008.docx

MON 89034 Label Dec 2008.docx

"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>
12/12/2008 09:23 AM

To Jeannine Kausch/DC/USEPA/US@EPA
cc
bcc
Subject RE: MON 89034 and MON 89034 x MON 88017 - Draft acceptance letters going up for signature/labels

Great, I will have something to you in the next 30 minutes.

Russ

-----Original Message-----
From: Kausch.Jeannine@epamail.epa.gov
[mailto:Kausch.Jeannine@epamail.epa.gov]
Sent: Friday, December 12, 2008 9:16 AM
To: SCHNEIDER, RUSSELL P [AG/1920]
Subject: RE: MON 89034 and MON 89034 x MON 88017 - Draft acceptance letters going up for signature/labels

Hi Russ,

An electronic copy of both labels is still sufficient for me at this time because the changes are minor. Once the acceptance letters are signed by Sheryl, I will print out the electronic copies that you provide, stamp them, and those will serve as your final, accepted labels.

Thanks,

Jeannine

"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>
12/12/2008 09:05 AM

To Jeannine Kausch/DC/USEPA/US@EPA
cc
Subject RE: MON 89034 and MON 89034 x MON 88017 - Draft acceptance letters going up for signature/labels

Jeannine,

Thanks. I will get back to you shortly. Do you want me to provide 3 hard copies of the label after we have revised it, or is an electronic

copy sufficient for your use, and the stamping of a final for us?

Russ

-----Original Message-----
From: Kausch.Jeannine@epamail.epa.gov
[mailto:Kausch.Jeannine@epamail.epa.gov]
Sent: Friday, December 12, 2008 8:56 AM
To: SCHNEIDER, RUSSELL P [AG/1920]
Subject: MON 89034 and MON 89034 x MON 88017 - Draft acceptance letters going up for signature/labels

Hi Russ,

I assembled both amendment packages to go up for signature yesterday and will give them to Sheryl this morning. Of course, that doesn't mean she will sign off on them today, but I am fairly confident that you will hear word back from me by next week. In regards to the two letters with the revised terms and conditions, I went through everything once more with Alan Reynolds of our IRM team yesterday and he asked me to make a few more modifications, none of which seem major in my mind. However, for your reference and review, I have included copies of the final letters and shown you the changes made, when compared to the copies that you previously looked at, and a brief explanation of why the changes were made. If you could respond back with an email letting me know that these final modifications are acceptable to Monsanto, I would appreciate it.

Also, I looked over the labels and they were satisfactory, but I would request that a few additional corrections be made. See the attached labels below for the comments. Please send the revised labels back to me via email as soon as the new revisions are integrated.

Please let me know if you have questions.

Thanks,
Jeannine

(See attached file: MON 89034 x MON 88017_Letter with minor modifications.pdf)(See attached file: MON 89034_Letter with minor modifications.pdf)(See attached file: Label MON 89034 x MON 88017 Dec 2008_2nd iteration of comments.docx)(See attached file: MON 89034 Label Dec 2008_2nd iteration of comments.docx)

Jeannine
Kausch/DC/USEPA/US
12/11/2008 11:29 AM

To "SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>
cc
bcc
Subject Re: FW: Response to EPA on MON 89034 and MON 89034 x MON 88017 amendments

Hi Russ,

Thanks for the updated labels and confirmation that Monsanto accepts the revised terms and conditions for MON 89034 and MON 88017 x MON 89034. I will work on finalizing the acceptance letters and looking over the revised labels today. I should have everything ready to go through the approval concurrence chain by the end of the day provided that no other issues arise.

Thanks,

Jeannine

"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>

"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>
12/11/2008 09:01 AM

To Jeannine Kausch/DC/USEPA/US@EPA
cc
Subject FW: Response to EPA on MON 89034 and MON 89034 x MON 88017 amendments

Jeannine,

Monsanto accepts the terms of conditions for the amendments requested for MON 89034 and MON 89034 X MON 88017 We have revised the labels of the two products per EPA's recommendations except the suggestion of including trade (brand, or line) names on the label. Given that Monsanto is in a process of revamping its master brand name which will affect the line names for products like MON 89034 x MON 88017, we will submit a notification for each product with alternate brand names in the near future.

Russ

Dr. Russell P. Schneider

Senior Director, Regulatory Affairs and Policy

Monsanto Company

1300 I St., NW

Suite 450 East

"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>

12/10/2008 01:30 PM

To Jeannine Kausch/DC/USEPA/US@EPA

cc

bcc

Subject RE: Acceptance Letter Draft and Label Comments for MON 89034 x MON 88017

Thanks Jeannine. As always this is probably no more than a couple of states with the issue, but they make it a problem for everyone. We will certainly make sure everyone knows that the registration belonging to a MON designation, corresponds to a specific brand name, and that brand name, under a specific EPA registration will be commercialized.

See you tomorrow.

Russ

-----Original Message-----
From: Kausch.Jeannine@epamail.epa.gov
[mailto:Kausch.Jeannine@epamail.epa.gov]
Sent: Wednesday, December 10, 2008 1:22 PM
To: SCHNEIDER, RUSSELL P [AG/1920]
Subject: RE: Acceptance Letter Draft and Label Comments for MON 89034 x MON 88017

Hi Russ,

Thanks for the update regarding my label comments. I am actually surprised that the states have a problem with the alternate brand names on the label provided that it is clearly delineated as such (e.g., alternate brand name: """). I know the Agency has occasionally had trouble keeping track of notification changes because a "stamped" label is not issued to the registrant. Following that, there is the question of whether the modified label with relevant documentation makes it onto our Pesticide Product Label System [PPLS], which is the system that the states and public use for reference. If they don't see approval of your alternate brand name indicated on PPLS, I would think it would cause a delay in processing your information. However, I will leave it up to you as to whether you want to include the alternate brand name now, with the appropriate identifier, or whether you would like to submit a notification after this amendment. Regardless, you must formally let the Agency that you are utilizing alternate brand names for both MON 89034 and MON 89034 x MON 88017 as both products are referred to with these names in the grower agreement and the technology use guide.

Thanks for asking for clarification. Let me know if you have any other questions.

Regards,

Jeannine

"SCHNEIDER, RUSSELL P

[AG/1920]"
<russell.p.schneider@monsanto.com>

12/10/2008 08:59 AM

To
Jeannine Kausch/DC/USEPA/US@EPA
cc

Subject
RE: Acceptance Letter Draft and Label Comments for MON 89034 x MON 88017

Jeannine,

I have not seen the labels from Yong Gao yet, but anticipate sending them to you today. One concern I have is adding an alternate brand name to the label for either product. The states have a real problem having both names on the same label. We think it would be best to have the label for the MON product approved, and submit a notification of an alternate brand name to you for the product. Does that cause you concern?

Russ

-----Original Message-----
From: Kausch.Jeannine@epamail.epa.gov
[mailto:Kausch.Jeannine@epamail.epa.gov]
Sent: Tuesday, December 09, 2008 9:49 AM
To: SCHNEIDER, RUSSELL P [AG/1920]
Subject: RE: Acceptance Letter Draft and Label Comments for MON 89034 x MON 88017

Hi Russ,

No, you don't have to make a formal label submission for either MON 89034 or MON 89034 x MON 88017. If you can make corrections for both labels and then send the corrected labels back to me via email, that is considered acceptable.

I don't know if you've looked through the label corrections yet, but please disregard my request to list the "other ingredients" for MON 89034 on the label. I did not have the opportunity to look over the CSF for the product until this morning and noticed my error in that there are no "other ingredients" to be listed.

Thanks,

Jeannine

"SCHNEIDER, RUSSELL P [AG/1920]"
<russell.p.schne

To
Jeannine Kausch/DC/USEPA/US@EPA

Jeannine Kausch/DC/USEPA/US
12/09/2008 09:49 AM

To "SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>
cc
bcc
Subject RE: Acceptance Letter Draft and Label Comments for MON 89034 x MON 88017

Hi Russ,

No, you don't have to make a formal label submission for either MON 89034 or MON 89034 x MON 88017. If you can make corrections for both labels and then send the corrected labels back to me via email, that is considered acceptable.

I don't know if you've looked through the label corrections yet, but please disregard my request to list the "other ingredients" for MON 89034 on the label. I did not have the opportunity to look over the CSF for the product until this morning and noticed my error in that there are no "other ingredients" to be listed.

Thanks,

Jeannine

"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>

"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>
12/09/2008 09:35 AM

To Jeannine Kausch/DC/USEPA/US@EPA
cc
Subject RE: Acceptance Letter Draft and Label Comments for MON 89034 x MON 88017

Jeannine,

I assume we should make a formal label submission for each product. Is that correct?

Russ

-----Original Message-----
From: Kausch.Jeannine@epamail.epa.gov
[mailto:Kausch.Jeannine@epamail.epa.gov]
Sent: Tuesday, December 09, 2008 7:51 AM
To: SCHNEIDER, RUSSELL P [AG/1920]
Subject: Acceptance Letter Draft and Label Comments for MON 89034 x MON 88017

Hi Russ,

With regards to responding to the letter and label comments for MON 89034 x MON 88017, the same explanation as provided yesterday for MON 89034 also applies in this case. Please look everything over in the draft letter and ensure that all the terms and conditions are acceptable and not confusing. The label comments mostly request that the language

"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>

12/08/2008 02:56 PM

To Jeannine Kausch/DC/USEPA/US@EPA

cc

bcc

Subject Re: Acceptance Letter Draft and Label Comments for MON 89034

Thanks Jeannine. It was a pleasure to meet you as well. I am sure we will see a lot of each other.

Russ

Sent from my BlackBerry Wireless Handheld

----- Original Message -----
From: Kausch.Jeannine@epamail.epa.gov <Kausch.Jeannine@epamail.epa.gov>
To: SCHNEIDER, RUSSELL P [AG/1920]
Sent: Mon Dec 08 13:45:53 2008
Subject: RE: Acceptance Letter Draft and Label Comments for MON 89034

Hi Russ,

You are correct. We have decided not to do a pre-acceptance letter with these amendments. Shipment of the product will constitute acceptance of the revised conditions, but you will still need to make the requested changes to the label. If you have concerns about the revision of the terms and conditions, please let me know in the next few days so that we may discuss before I send the letter up for management approval.

It was good to finally meet you and thanks again for the Cry3Bb1 information.

Thanks,

Jeannine

"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>

12/08/2008 11:52 AM

To Jeannine Kausch/DC/USEPA/US@EPA

cc

Subject RE: Acceptance Letter Draft and Label Comments for MON 89034

Jeannine,

The way your draft letter reads, we do not need to send an acceptance to this letter, only a change to the label is required. Shipment of product constitutes agreement with the conditions. Only if we have proposed changes or concerns is a response to the conditions necessary. Is that correct?

Russ

-----Original Message-----
From: Kausch.Jeannine@epamail.epa.gov
[mailto:Kausch.Jeannine@epamail.epa.gov]
Sent: Monday, December 08, 2008 11:41 AM
To: SCHNEIDER, RUSSELL P [AG/1920]
Subject: Acceptance Letter Draft and Label Comments for MON 89034

Hi Russ,

Please find attached a copy of the draft acceptance letter for MON 89034, along with requested corrections to the label. The terms and conditions have been updated to reflect the most recent ABSTC language and that Monsanto has submitted certain requested information. Because the terms and conditions have been updated, there are also corrections that involve standardizing and clarifying language on the label. Let me know if you have any questions. I hope to have the MON 89034 x MON 88017 draft letter and label comments to you by this afternoon or tomorrow.

Thanks,

Jeannine

(See attached file: MON 89034_Amendment_12-01-2008.doc)(See attached file: Requested Changes for MON 89034.doc)

DRAFT

Dr. Russell P. Schneider
Senior Director, Regulatory Affairs and Policy
Monsanto Company
1300 I Street, NW, Suite 450 East
Washington, DC 20005

Re: Monsanto Company, MON 89034
EPA Registration No. 524-575
Amendment to Allow for 5% Structured Refuge in the Corn Belt (Non-Cotton Growing Regions) for Corn Borers
Submission dated 06/11/2008

Dear Dr. Schneider:

The amendment referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided that you comply with the following terms and conditions.

1) The subject registration will automatically expire on midnight September 30, 2010.

2) The subject registration will be limited to MON 89034 in field or sweet corn. Further, MON 89034 sweet corn may only be sold directly to processors or through commercial dealers to large growers. MON 89034 sweet corn must not be sold to small roadside or home growers.

3) Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.

4) This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

DRAFT

5) Submit the following data in the time frames listed:

OPPTS Guideline/ Study Type	Required Data	Due Date
Residue Analytical Method – Plants (OPPTS 860.1340)	For event MON 89034 corn, an independent lab validation of the analytical method for the detection of Cry2Ab2 and/or Cry1A.105. You must also agree to provide to the EPA laboratory (Ft. Meade, MD) methodology and/or reagents necessary for validation of such analytical method within 6 months from the date that the Agency requests them.	4/1/2009
Aquatic Invertebrate Acute Toxicity Testing, Freshwater *Daphnids* (OPPTS 885.4240)	A 7-14 day *Daphnia* study as per the 885 Series OPPTS Guidelines needs to be performed. Alternatively, a dietary study of the effects on an aquatic invertebrate, representing the functional group of a leaf shredder in headwater streams, can be performed and submitted in lieu of the *Daphnia* study.	4/1/2009
Insect Resistance Management – Resistance Monitoring	Monsanto must provide additional information on cross-resistance of Cry1A.105 and Cry1Ac (preferably including binding site models and use of resistant colonies) for the target pests and determine how such cross-resistance may impact the durability of MON 89034, including any impacts in the southern cotton-growing areas. The Cry1A.105 protein is a chimeric protein consisting of Domains I and II and the C-terminus of Cry1Ac. It is important to address not only the likelihood of cross-resistance potential of Cry1A.105 and Cry1Ab and, similarly, Cry1A.105 and Cry2Ab2 (which was done by Monsanto) but also that of Cry1A.105 and Cry1Ac.	4/1/2009
Insect Resistance Management – Resistance Monitoring	Baseline susceptibility studies and/or a discriminating concentration assay are required for the Cry1A.105 protein against European corn borer (ECB), Southwestern corn borer (SWCB), and corn earworm (CEW) and for the Cry2Ab2 protein against SWCB and CEW.	4/1/2009

DRAFT

OPPTS Guideline/ Study Type	Required Data	Due Date
Insect Resistance Management – Resistance Monitoring	To support sweet corn uses, baseline susceptibility studies must be conducted on fall armyworm (FAW) populations collected from sweet corn growing areas. Monitoring studies will be conducted on FAW populations collected from sweet corn distribution areas in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 1000 acres. The collected populations of FAW will be monitored for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins.	4/1/2010

6) The Insect Resistance Management (IRM) terms and conditions for this product are as follows.

The required IRM program for MON 89034 must have the following elements:

- Requirements relating to creation of a non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuge in conjunction with the planting of any acreage of MON 89034 field corn;
- Requirements for Monsanto to prepare and require MON 89034 users to sign "grower agreements," which impose binding contractual obligations on the grower to comply with the refuge requirements;
- Requirements regarding programs to educate growers about IRM requirements;
- Requirements regarding programs to evaluate and promote growers' compliance with IRM requirements;
- Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1A.105 and Cry2Ab2 proteins in the target insects;
- Requirements regarding a "remedial action plan," which contains measures Monsanto would take in the event that any field relevant insect resistance was detected as well as to report on activity under the plan to EPA;
- Submit annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreement results, and the compliance assurance program including the education program on or before January 31st each year, beginning in 2010.

DRAFT

a) Refuge Requirements for MON 89034 Field Corn

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year. Furthermore, these refuge requirements do not apply to commercial hybrid sweet corn.

1) Corn-Belt Refuge Requirements

For MON 89034 field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 5% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.

- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.

- External refuges must be planted within ½ mile.

- When planting the refuge as strips across the field or as perimeter strips, refuges must be at least 4 rows wide.

- Insecticide treatments for control of ECB, CEW, SWCB, and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

DRAFT

2) Cotton-Growing Area Refuge Requirements

For MON 89034 field corn grown in cotton-growing areas, grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/ product use guide.

- Specifically, growers in these areas must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.

- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.

- External refuges must be planted within ½ mile.

- When planting the refuge as strips across the field or as perimeter strips, refuges must be at least 4 rows wide.

- Insecticide treatments for control of ECB, CEW, SWCB, and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

- Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex), and Missouri (only the counties of Dunkin, New Madrid, Pemiscot, Scott, and Stoddard).

DRAFT

b) Post-Harvest Requirements for MON 89034 Sweet Corn

Sweet corn is harvested long before field corn. Therefore, if the sweet corn stalks remaining in the field and any insects remaining in the stalks are destroyed shortly after harvest, a refuge is not needed as a part of the IRM program for sweet corn. Growers must adhere to the following types of crop destruction requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Crop destruction must occur no later than 30 days following harvest, but preferably within 14 days.

- The allowed crop destruction methods are: rotary mowing, discing, or plow-down. Crop destruction methods should destroy any surviving resistant insects.

c) Grower Agreements for MON 89034

1) Persons purchasing MON 89034 must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3) Monsanto must integrate this registration into the current system used for their other *Bt* corn PIPS, which is reasonably likely to assure that persons purchasing MON 89034 will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4) Monsanto must continue to use their current grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

5) Monsanto must integrate this registration into a current system, which is reasonably likely to assure that persons purchasing MON 89034 sign grower agreement(s).

6) Monsanto shall maintain records of all MON 89034 grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

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7) Beginning on January 31, 2010 and annually thereafter, Monsanto shall provide EPA with a report showing the number of units of MON 89034 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July. Note: The first report shall contain the specified information from the time frame starting with the date of registration and ending July 31, 2009.

8) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

d) IRM Education and Compliance Monitoring Programs for MON 89034

1) Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to MON 89034 users the importance of complying with the IRM program. The program shall include information encouraging MON 89034 users to pursue optional elements of the IRM program relating to refuge configuration and proximity to MON 89034 fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each MON 89034 user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraphs 6a or 6b and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) On January 31, 2010, Monsanto must provide a report to EPA summarizing the activities carried out under the education program for the prior year. Annually thereafter, Monsanto must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Monsanto must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC).

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4) Monsanto must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing MON 89034 are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to MON 89034. Monsanto shall coordinate with other *Bt* corn registrants in designing and implementing its compliance assurance program and integrate this registration into the current compliance assurance program used for their other *Bt* corn PIPS. Other required features of the program are described in paragraphs 5 – 15 below.

5) Monsanto must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how they will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Monsanto must use a consistent set of standards for responding to non-compliance. The options shall include withdrawal of the right to purchase Monsanto corn PIP products for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of Monsanto corn PIP products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Monsanto corn PIP products.

6a) MON 89034 Field Corn: The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of MON 89034 field corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the United States.

6b) MON 89034 Sweet Corn: The IRM compliance assurance program shall include an annual survey of all MON 89034 sweet corn customers who purchase 5 or more bags of MON 89034 sweet corn. The survey shall measure the degree of compliance with the IRM program, identify the response rate (e.g., the percent of MON 89034 sweet corn acres covered by the responses), and consider the potential impact of non-response. An independent third party will participate in the design and implementation of the survey. Data and information derived from the annual survey will be audited by an independent third party.

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7) The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8) The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9a) MON 89034 Field Corn: Monsanto shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31st of each year, beginning in 2010. Monsanto shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

9b) MON 89034 Sweet Corn: Monsanto shall provide a written summary of the results of the prior year's survey (together with a description of the methodology used and the supporting data) to EPA by January 31st of each year, beginning in 2010. Monsanto shall confer with EPA on changes to the design and content of the survey prior to its implementation.

10) Annually, Monsanto shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs 6a through 8 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Monsanto must confer with the Agency prior to adopting any changes.

11) Monsanto shall conduct an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with growers of MON 89034 to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

12) Monsanto shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach."

13) If a grower, who purchases MON 89034 for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

14) Beginning January 31, 2010 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. Monsanto may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

15) Monsanto and the seed corn dealers for Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

e) Insect Resistance Monitoring and Remedial Action Plan for MON 89034

The Agency is imposing the following conditions for this product:

Monsanto will monitor for resistance to MON 89034. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing and (2) investigation of reports of less-than expected control of labeled insects. Should field relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

(1) Focused Population Sampling

Monsanto will develop and ensure the implementation of a plan for resistance monitoring for *Spodoptera frugiperda* (fall armyworm or FAW) in counties in which MON 89034 / MON 89034 x MON 88017 sweet corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. Monsanto should consult with academic and United States Department of Agriculture (USDA) experts in developing the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31st of the year following that in which MON 89034 / MON 89034 x MON 88017 sweet corn acreage exceeds the trigger specified in this requirement (i.e., greater than 5,000 acres in any county in which FAW overwinters). The proposed plan must be implemented the season following the acreage trigger being met. The proposed plan will remain in place until an EPA approved plan can be implemented.

Monsanto shall annually sample and bioassay populations of the key target pests: *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where

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lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to MON 89034 and/or changes in resistance-allele frequency in response to the use of MON 89034 and, as far as possible, should be consistent across sampling years to enable comparisons with historical data. Each protein in MON 89034 must be tested separately, rather than a mixture of the two proteins, because resistance to one protein could be masked by the activity of the other.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of MON 89034. The Agency shall be consulted prior to the implementation of such modifications.

The registrant will report to the Agency by August 31st of each year, beginning in 2010, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1A.105 and Cry2Ab2 proteins in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31st, beginning in 2010. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.

2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to MON 89034 under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.

3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to taken to evaluate the resistance. These steps may include:

- determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);
- estimating the resistance-allele frequency in the original population;
- determining whether the resistance-allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
- determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Monsanto will consult with the Agency to develop and implement a case-specific resistance management action plan.

(2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:

Monsanto will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Monsanto will instruct its customers to contact them if such incidents occur. Monsanto will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, CEW, and FAW), Monsanto will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance.*

Suspected resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;

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- the relevant plant tissues are expressing the expected level of *Bt* protein; and

- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to MON 89034 in commercial production fields before responsive measures are undertaken.

If resistance is *suspected,* Monsanto will instruct growers to do the following:

- Use alternative control measures in MON 89034 fields in the affected region to control the target pest during the immediate growing season.

- Destroy MON 89034 crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, Monsanto will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).

- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance-allele frequency of ≥ 0.1 in the sampled population.

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- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

(3) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is *confirmed* (as defined above), the following steps will be taken by Monsanto:

- EPA will receive notification within 30 days of resistance confirmation;

- Affected customers and extension agents will be notified about confirmed resistance within 30 days;

- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;

- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;

- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;

- Monsanto will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Monsanto will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;

- Notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and

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- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year, beginning in 2010, for the duration of the conditional registration.

g) Annual Reporting Requirements for MON 89034

1) Annual Sales: reported and summed by state (county level data available by request), January 31st each year, beginning in 2010;

2) Grower Agreement: number of units of MON 89034 seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year, beginning in 2010;

3) Grower Education: substantive changes to education program completed previous year, January 31st each year, beginning in 2010;

4) Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year, beginning in 2010;

5) Compliance Survey Results: to include annual survey results and plans for the next year; full report January 31st each year, beginning in 2010;

6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2010.

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If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of this product constitutes acceptance of these conditions. If you have any questions contact Jeannine Kausch at 703-347-8920 or by email at: kausch.jeannine@epa.gov.

A stamped copy of the label is enclosed for your records.

Sincerely,

Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure (1):
-Accepted Label

Requested Changes for MON 89034 (#524-575) Label
(Some of the changes are reflected in blue.)**

1) If there is intention to use an alternate brand name for MON 89034 (i.e., YieldGard VT PRO™ corn) as is shown in the grower agreement sample that you submitted, this must be indicated on the label under the primary brand name. For example:

MON 89034
(alternate brand name: YieldGard VT PRO™ corn)

2) Please make the following modifications to the INGREDIENT STATEMENT:

- For the Cry1A.105 protein, please indicate the same number of significant digits throughout the range of the active ingredient component (e.g., 0.0020 – 0.0056%).

- Please indicate the other ingredients, similar to the most recently accepted MON 88017 label dated 06/10/2008. For example:

DISREGARD → NO "OTHER INGREDIENTS" TO LIST!

Other Ingredients:

Substance produced by a marker gene and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn…..percentage range

- Please include an asterisk after all percentage ranges listed in the INGREDIENT STATEMENT (for ~~both~~ active and ~~other~~ ingredient~~s~~) and before the statement, "Percentage (wt/wt) on a dry weight basis whole plant (forage)."

3) Please resituate the label so that the KEEP OUT OF REACH OF CHILDREN statement is located above the signal word, CAUTION.

4) Please change the statement "MON 89034 can be crossed with events MON 88017, TC1507, or DAS-59122-7 to produce combined trait corn products" to the following statement (per the updated terms and conditions):

"This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits."

5) Please insert the sub-heading, **1) Refuge Requirements for MON 89034 Field Corn**, after the 3rd set of statements in the Directions for Use.

**This has been requested in order to remove the post-harvest requirements for sweet corn from the "refuge requirements" and place them in their own section.

6) Please change the wording in the 4th set of statements under the Directions for Use to the following for clarification:

"In order to minimize the risk of corn borers developing resistance to MON 89034 field corn, an insect resistance management plan must be implemented, which includes planting of a structured refuge."

**Statement "these pests" is referring back to the 2nd set of statements under the Directions for Use but could use specification because of the intervening language between the above language and the language it is referring back to.

7) Please change the statement "These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn and small scale research trials for observation, nor to commercial hybrid seed corn" to the following statement (per the updated terms and conditions):

"These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year. Furthermore, these refuge requirements do not apply to commercial hybrid sweet corn."

8) Please change the sub-heading, **a) Corn-Belt/Non-Cotton Growing Areas**, to the sub-heading, **a) Corn-Belt/Non-Cotton Growing Area Refuge Requirements.**

9) Under "**Corn-Belt/Non-Cotton Growing Area Refuge Requirements**," please remove the 1st set of statements as this has been separated into another section.

10) Under "**Corn-Belt/Non-Cotton Growing Area Refuge Requirements**," please change the current 2nd set of statements to the following:

"For MON 89034 field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower guides must specify that growers must adhere to the following refuge requirements. Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products."

"Growers must plant a structured refuge of at least 5% corn, which is not a lepidopteran-protected Bt corn hybrid. The refuge may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests."

11) Under "**Cotton-Growing Area Refuge Requirements**," please remove the current 2nd set of statements as this has been separated into another section.

12) Under "**Cotton-Growing Area Refuge Requirements**," please change "lepidopteran-protected Bt field corn" to "MON 89034 field corn." Also, please add the following sentence, "Growers who fail to comply with the IRM requirements risk losing

access to Monsanto co IP products," after the corrected sente (Matching the statement found under the Corn-Belt Refuge Requirements section).

13) Under "**Cotton-Growing Area Refuge Requirements**," please change the 2nd sentence in the current 4th set of statements to the following:

"The refuge may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests."

14) Under "**Cotton-Growing Area Refuge Requirements**," please arrange the diagrams and statements detailing refuge types, external refuge distance, and strip refuge explanation as is done in the Corn-Belt Refuge Requirements section for consistency and clarity.

15) Under "**Cotton-Growing Area Refuge Requirements**," please remove "(1/4 mile or closer preferred)" from the current 6th set of statements.

16) Immediately follow the Cotton-Growing Area Refuge Requirements section, but before the Corn Insects Controlled section, please insert the following statements referring to use of MON 89034 in sweet corn:

2) Post-Harvest Requirements for MON 89034 Sweet Corn

For MON 89034 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, discing, or plow-down within one (1) month of harvest.

"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>
12/04/2008 02:44 PM

To Jeannine Kausch/DC/USEPA/US@EPA
cc
bcc
Subject RE: 5% refuge for MON 89034

Jeannine,

Thank you very much. We look forward to seeing the draft.

Russ

-----Original Message-----
From: Kausch.Jeannine@epamail.epa.gov [mailto:Kausch.Jeannine@epamail.epa.gov]
Sent: Thursday, December 04, 2008 2:30 PM
To: SCHNEIDER, RUSSELL P [AG/1920]
Subject: Re: 5% refuge for MON 89034

Hi Russ,

I was going to call you and provide you with a status but will instead try to explain, in this email, what stage I am in with regards to drafting the letters for the 5% refuge for MON 89034 and MON 89034 x MON 88017. I have been working with Alan to capture the relevant elements of the amendment, which has not been problematic. However, I am also updating the terms and conditions of the original registration notice of both products to reflect that various conditions have been submitted, to reflect certain cross resistance concerns that have been addressed (between Cry1A.105 and Cry1Fa), to clarify certain points, and to standardize the terms and conditions in accordance with the most recent ABSTC language. I am almost done drafting the letters but please be aware that there are still several steps before approval as I need to ensure the labels match the terms and conditions of both registrations and the letters need to go through management. Also, I would like to send you a draft copy of the letters, so that you know what is being altered from the original registration notices. I expect to get draft copies of acceptance letters and any comments I have on the labels by the middle of next week.

Thanks,

Jeannine

Environmental Protection Specialist
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
(703) 347-8920 (telephone)
(703) 305-0118 (fax)

"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>

To Jeannine Kausch/DC/USEPA/US@EPA
cc

	Subject
12/04/2008 01:47 PM	5% refuge for MON 89034

Jeannine,

Per Mike's earlier note, I wanted to check on the status of the 5% refuge request for MON 89034. In one of my last meetings with Alan and Sheryl they indicated the review was completed and I was hoping a decision had been made. Do you know when we will hear from your agency?

Russ

Jeannine
Kausch/DC/USEPA/US
12/02/2008 01:29 PM

To Alan Reynolds/DC/USEPA/US@EPA
cc
bcc
Subject Draft Amendment Acceptance Letters for MON 89034 and Mon 89034 x MON 88017

Hi Alan,

It took me some time to integrate everything from the ABSTC standardized registrations, but I think I captured the appropriate items for field and sweet corn in both amendment letters. Additionally, I made the appropriate changes to reflect the permitted reduction for corn borer refuge for the Corn Belt and that Monsanto met the requirements for evaluating cross resistance (for now) of Cry1A.105 and Cry1Fa. However, I would appreciate if you still look over both letters for accuracy and consistency as I am prone to mistakes, in general, but particularly after looking at something for too long.

Would you also be able to look at two specific items (that appear on the original registration notices) that I've included in the current letters but have some questions about?

a) On page 11 of the MON 89034 letter, why did we ask the registrant to follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm? I thought the two proteins in MON 89034 specifically targeted only lepidopteran pests, so why the concern about resistance in corn rootworm? Perhaps, a stupid question, but I am just curious as to why we would include that requirement for MON 89034.

b) On page 5 of the MON 89034 letter, the last requirement in the table refers to cross-resistance concern in southern cotton-growing areas, but it seems to describe the same concept as is provided in the box above it, which references to cross resistance with other proteins in other *Bt* corn and cotton plants. Is there a difference that I am missing?

Your red ink input is much appreciated.

Thanks,

Jeannine

**Jeannette does not have the hard copies of the data packages for this amendment and did not get them from you for her peer review. Wonder where they could be?


MON 89034 x MON 88017_Amendment_12-01-2008.doc


MON 89034_Amendment_12-01-2008.doc

Alan Reynolds/DC/USEPA/US
11/12/2008 06:46 PM

To Jeannine Kausch/DC/USEPA/US@EPA
cc Jeannette Martinez/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA
bcc
Subject MON 89034 amendment - completed review

Hi Jeannine-

I'm attaching an electronic copy of the MON 89034 review -- the original is on your chair. Mike- please use this version for archiving in ARS.

Jeannette-

Did I give you the MRID volume for the secondary review? If so, can you please give it to Jeannine?

Also, after much thought, I decided that your major comment (i.e. modeling using Cry1Ab and assuming complete cross resistance) is more relevant to ECB. Our primary concern with Cry1Ac and cross resistance to Cry1A.105 is with CEW (which was not included in the modeling). Therefore, I left the review as is....we can discuss further when I see you next at ESA

Alan

MON 89034 - amendment.doc

Alan Reynolds
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MEMORANDUM

SUBJECT: Review of an amendment request to reduce the refuge required for MON 89034 corn in the Corn Belt.
EPA Reg No. 524-575 and 524-576. MRID#: 474748-01.
Decision#: 394797. DP Barcode: 354723.

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Action Requested

BPPD[1] has been asked to review an amendment request submitted by Monsanto Company to reduce the required refuge for MON 89034 Bt corn (EPA Reg. No. 524-575) and MON 89034 x MON 88017 Bt corn (524-576) in the Corn Belt. MON 89034 was initially registered with a requirement to plant a 20% refuge in the Corn Belt; Monsanto is proposing to reduce the percent refuge to 5% in these areas. In support of the amendment request, Monsanto submitted data and an analysis of potential resistance risk in a volume titled "Assessment of the Impact of MON 89034 Introduction on Bt Resistance Development in European and Southwestern Corn Borer" (MRID# 474748-01).

Conclusions and Recommendations

1) Monsanto's request to reduce the required non-Bt corn refuge for MON 89034 corn from 20% to 5% is scientifically supported by the submitted cross resistance information and model simulations and should not significantly increase the risk of resistance for

[1] The use of BPPD in this review refers to the BPPD IRM Team consisting of Alan Reynolds and Jeannette Martinez

European corn borer (ECB) and southwestern corn borer (SWCB). While there are still some uncertainties regarding the refuge reduction (described below in # 3-5), the overall conclusions and recommendations are not affected.

2) BPPD notes that this request pertains only to MON 89034 grown in the U.S. Corn Belt; MON 89034 grown in southern cotton-growing regions (as defined by the terms and conditions of registration) is unaffected by this amendment and must be planted with a 20% non-Bt corn refuge. Although not formally addressed in the submission, the conclusions of this review are also applicable to the lepidopteran refuge portion of the MON 89034 x MON 88017 registration (EPA Reg. No. 524-576).

3) As a condition of registration of MON 89034, Monsanto was required to analyze potential cross resistance in existing Bt corn and Bt cotton products for Cry1A.105, Cry1Fa and Cry1Ac. Monsanto has sufficiently addressed cross resistance for Cry1A.105 and Cry1Fa in this submission, but insufficient analysis was provided for Cry1Ac and Cry1A.105. So that BPPD can fully assess the cross resistance potential of Cry1A.105 with Cry1Ac, it is recommended that Monsanto provide additional information either experimentally (i.e. binding studies or with resistant colonies) or using another analysis.

4) Potential cross resistance between Cry1A.105 with Cry1Ac is an issue primarily for the corn earworm (CEW), which feeds on corn and cotton and could be exposed to both Cry1A.105 (in MON 89034 corn) and Cry1Ac (in Bollgard cotton). However, several factors reduce the likelihood of CEW resistance developing to MON 89034 corn with a 5% refuge: 1) CEW is not as prominent a pest in the Corn Belt as ECB; 2) CEW does not overwinter well in the Corn Belt; 3) CEW is highly polyphagous (feeding on numerous crops and wild hosts) and there may be some degree of natural refuge in the Corn Belt.

5) BPPD noted several limitations to the model simulations used to support the amendment: 1) No model simulations were conducted to compare 5% (proposed) vs. 20% (current) refuge for MON 89034; 2) The model time horizon (30 years) limited comparisons between many of the model scenarios; 3) SWCB scenarios included dose mortality estimates somewhat higher than those suggested by previously-submitted data. While BPPD believes the model analysis would have been improved had these areas been addressed, the impact on the model output would likely not have been great enough to alter the overall conclusions.

6) Since MON 89034 is an expiring registration (expiration date: September 30, 2010), BPPD recommends reevaluating the 5% refuge if warranted by cross resistance data or other information received during this interim period.

Background

MON 89034 and MON 89034 x MON 88017 are plant-incorporated protectants (PIP) that were registered for commercial use on June 10, 2008. Event MON 89034 contains

two proteins (Cry1A.105 and Cry2Ab2) that are targeted against lepidopteran corn pests including European corn borer (*Ostrinia nubilalis*, ECB), corn earworm (*Helicoverpa zea*, CEW), southwestern corn borer (*Diatraea grandiosella*, SWCB), and fall armyworm (*Spodoptera frugiperda*, FAW). MON 88017 was registered separately in 2003 and controls corn rootworm (*Diabrotica* sp., CRW).

As part of the IRM proposal for MON 89034 corn, Monsanto proposed a 5% lepidopteran structured refuge for non-cotton growing regions instead of the 20% refuge that has been required for all other Bt corn registrations. Monsanto reasoned that the combination of two toxins targeting lepidopteran corn pests with no cross resistance allowed for a reduced refuge with little risk of resistance. BPPD's review of the IRM proposal (BPPD 2007) agreed with much of Monsanto's justification but determined that there were a number of uncertainties in the request for lower refuge. Specifically, there were three areas of concern: 1) Cry1A.105 and Cry2Ab2 dose determination for the major target pests (ECB, CEW, SWCB, and FAW); 2) cross resistance potential between Cry1A.105 and Cry1F and Cry1Ac (toxins expressed in previously-registered PIPs); and 3) species-specific (e.g, ECB and SWCB for the Corn Belt), spatially-explicit, landscape modeling to explore the durability of MON 89034 versus single-protein Bt corn products. Given the uncertainty of the reduced refuge request, EPA registered MON 89034 with a 20% structured refuge requirement, similar to other Bt corn products. Separately, EPA did agree with Monsanto's request to reduce refuge in cotton-growing areas from 50% to 20% (see discussion in BPPD 2007). As a condition of registration, Monsanto was required to address cross resistance in existing Bt corn and Bt cotton products for Cry1A.105, Cry1Fa and Cry1Ac.

Monsanto has subsequently materials to address these three areas of uncertainty as part of a new amendment request for a reduced 5% refuge for non-cotton regions. The response, including a discussion of cross resistance and a new model, is included in a study titled "Assessment of the Impact of MON 89034 Introduction on Bt Resistance Development in European and Southwestern Corn Borer" (MRID# 474748-01).

Monsanto's Proposed Amendment to Support a 5% Refuge for MON 89034

Monsanto's proposal for a 5% refuge with MON 89034 includes two major components: 1) a discussion of the cross resistance potential between the toxins in MON 89034 and 2) a deterministic model to simulate a 5% refuge and the risk of resistance for ECB and SWCB. Each of these sections is described and reviewed individually below.

In lieu of submitting new dose determination data for Cry2Ab2 and Cry1A.105 for the major target pests, Monsanto has used the existing dose information (submitted for the original registration) in the new simulation model. Therefore, Monsanto's response to the dose determination uncertainties (detailed in BPPD 2007) will be discussed and reviewed in the modeling section below.

1) Cross Resistance Potential

MON 89034 contains both Cry1A.105 and Cry2Ab2, which target the same lepidopteran corn pest complex. The Cry1A.105 toxin is a "chimeric" protein containing domains I and II and the C-terminal from Cry1Ac and domain III from Cry1Fa while the Cry2Ab2 protein is the same as that currently expressed in Monsanto's Bollgard II cotton. Monsanto has sufficiently demonstrated that the cross resistance potential between these two proteins should be low, primarily due to differing modes of action (see discussion in BPPD 2007). However, in evaluating new PIP traits, the landscape of previously-registered toxins in the same crop must be taken into account. In addition, for corn PIPs, cotton must also be considered because one of the key target pests, corn earworm (also referred to as cotton bollworm, CBW, when a pest on cotton), is a pest of both crops. As a condition of registration, Monsanto was required to address cross resistance in existing Bt corn and Bt cotton products for Cry1A.105, Cry1Fa and Cry1Ac.

Monsanto's amendment submission for MON 89034 contained a discussion of cross resistance including an analysis of previous studies as well as a summary of recently developed data. Analysis of existing data was conducted for four toxin combinations: 1) Cry1Ab vs. Cry1Ac; 2) Cry1F vs. Cry1Ab and Cry1Ac; 3) Cry2Ab2 vs. Cryl proteins; and 4) Cry1A.105 vs. Cry1Ab and Cry1Ac. New data were presented for comparisons between Cry1A.105 and Cry2Ab2 vs. Cry1F.

Cry1Ab vs. Cry1Ac: Based on a literature review of binding studies with numerous lepidopteran species, Cry1Ac is known to have strong cross resistance with Cry1Ab. Both toxins share a high affinity binding site in ECB, CEW/CBW, SWCB, FAW, and others (references cited in MRID# 474748-01).

Cry1F vs. Cry1Ab and Cry1Ac: Cry1F also shares a binding site with Cry1Ab/Cry1Ac, though the level of cross resistance between Cry1F and Cry1A is not as strong as Cry1Ab vs. Cry1Ac. ECB resistant to Cry1Ab have been shown to be partially resistant to Cry1F although Cry1F resistant ECB were not cross resistant to Cry1Ab and only slightly resistant to Cry1Ac. Similar trends have also been shown with tobacco budworm (*Heliothis virescens*, TBW) (references cited in MRID# 474748-01). Overall, Cry1F can be considered partially cross resistant to Cry1Ab and Cry1Ac. The availability of binding sites may explain the partial cross resistance: Cry1Ab and Cry1Ac could have more different sites to bind with than Cry1F so that resistance to Cry1F still allows for some binding of Cry1Ab or Cry1Ac.

Cry2Ab vs. Cryl proteins: A literature review suggests that Cry2Ab has no cross resistance potential with any of the currently registered Cryl proteins including Cry1Ab and Cry1Ac. Studies have been conducted with numerous cotton pests including CEW, TBW, pink bollworm (*Pectinophora gossypiella*, PBW), and *Helicoverpa armigera* that revealed no shared binding sites between Cry2A and Cry1Ab or Cry1Ac proteins. Additional studies with Cry1Ac-resistant TBW, CEW/CBW, and PBW found no cross resistance with Cry2Ab (references cited in MRID# 474748-01). Previously submitted data by Monsanto for MON 89034 (Head 2006; reviewed in BPPD 2007) demonstrated that Cry1Ab-resistant ECB were not found to be cross resistant with Cry2Ab while Cry2Ab2-resistant *H. armigera* were not cross resistant with Cry1A.105 or Cry1Ac.

Cry1A.105 vs. Cry1Ab and Cry1Ac: For Cry1Ab, a previously submitted binding study with ECB (Head 2006; reviewed in BPPD 2007) showed that the protein has a distinct binding site from Cry1A.105. This was confirmed by studies with Cry1Ab-resistant ECB and sugarcane borer (*Diatraea saccharalis*, SCB) that showed no cross resistance with Cry1A.105. Monsanto argues that due to similar characteristics between Cry1Ab and Cry1Ac (i.e. mode of action), it is reasonable to assume that Cry1Ac should not be cross resistant with Cry1A.105. However, no binding studies or experiments with resistant colonies were described to verify that assumption.

Cry1A.105 and Cry2Ab2 vs. Cry1F: New data were cited by Monsanto (Schlenz et al. 2008) to assess the cross resistance potential between Cry1A.105/Cry2Ab2 and Cry1F using Cry1F-resistant ECB and FAW colonies. Artificial diet bioassays were used to test Cry1A.105, Cry2Ab2, and control groups against ECB and FAW colonies previously selected for high-level Cry1F resistance as well as unselected control colonies. A range of five concentrations was used and the test was conducted over a seven day period to determine growth inhibition (GI_{50}) for each colony. The results showed that, as expected, Cry1F-resistant ECB and FAW were not cross resistant with Cry2Ab2 -- the GI_{50} resistance ratios (Cry1F-resistant : Cry1F-susceptible) were 1.4 for ECB and 0.11 for FAW. With Cry1A.105, the GI_{50} resistance ratios were > 3.9 for ECB and 7.0 for FAW, indicating low level cross resistance.

Table 1: Cross resistance potential of MON 89034 (Cry1A.105 and Cry2Ab2) with previously registered Bt corn toxins.

	Bt toxins in MON 89034	
Existing Bt toxins	**Cry1A.105**	**Cry2Ab2**
Cry1Ab	No cross resistance (ECB, SCB)	No cross resistance (ECB)
Cry1Ac	Unlikely cross resistance, but unverified experimentally	No cross resistance (TBW, PBW, CEW/CBW)
Cry1F	Low level cross resistance (ECB, FAW)	No cross resistance (ECB, FAW)

BPPD Review - Cross Resistance

BPPD agrees with Monsanto's characterization of the cross resistance potential for the Cry1A.105 and Cry2Ab2 toxins with 1) each other (previously demonstrated in Head 2006), 2) Cry1F, and 3) Cry1Ab. Binding and resistant colony work conducted by Monsanto and other researchers clearly show that no cross resistance can be expected between Cry1A.105, Cry2Ab2 and Cry1Ab (see Table 1 above). New data referenced in Monsanto's amendment request also experimentally demonstrate the cross resistance potential between Cry1F and Cry2Ab2 (no cross resistance) and Cry1A.105 (low cross resistance).

However, BPPD still has reservations about Cry1Ac. While Monsanto has made the case that Cry1Ac should be expected to behave like Cry1Ab due to a similar mode of action, no experimental data (i.e. binding studies or bioassays with resistant insect colonies) were provided either in the original MON 89034 IRM submission (Head 2006) or the follow-up amendment request (MRID# 474748-01). BPPD notes that Cry1A.105 (a chimeric protein) contains domains I and II and the C-terminal from Cry1Ac. Cross-resistance could result when proteins share key structural features, which allows one resistance mechanism to confer resistance to more than one protein (Tabashnik, 1994; Gould et al., 1995).

BPPD recognizes that at the present time there are no registered Bt corn products containing Cry1Ac. Therefore, exposure to ECB and SWCB to Cry1Ac is unlikely, as neither is known as a cotton pest. FAW may occasionally feed on cotton, but favor corn and is also unlikely to have much exposure to Cry1Ac. On the other hand, successive generations of CEW may feed on both corn and cotton during the same growing season. This could result in a potential "double" exposure to Bt cotton (including Cry1Ab) and Bt corn (including Cry1A.105) and increased selection pressure for resistance, particularly if there is a risk of cross resistance.

Given that Monsanto has proposed to substantially reduce refuge for MON 89034 from 20% to 5%, cross resistance is an important consideration even for Cry1Ac. Although improbable, BPPD cannot rule out that a CEW/CBW population could develop Cry1Ac resistance in cotton and then encounter MON 89034 corn. [Tabashnik et al. (2008) have argued that Cry1Ac resistance has already evolved in CBW in the south, although this conclusion has been disputed (Moar et al. 2008).] Should there be a degree of cross resistance between Cry1Ac and Cry1A.105, MON 89034 might functionally have only Cry2Ab2 remaining as an effective toxin against CEW. With a reduced refuge (5%), selection pressure could be increased for resistance to MON 89034 and Cry2Ab2 (which also is expressed in Bollgard II cotton). So that BPPD can fully assess the cross resistance potential of Cry1A.105 with Cry1Ac in CEW/CBW, it is recommended that Monsanto provide additional information either experimentally (i.e. binding studies or with resistant colonies) or using another analysis. Alternatively, Monsanto could revise the CEW model submitted with the original MON 89034 IRM plan (Head 2006) to support 20% refuge in cotton-growing regions. This model simulated CEW resistance to MON 89034 and assumed complete cross resistance between Cry1A.105 and Cry1Ac; the model could be adapted to evaluate a 5% refuge in the Corn Belt with similar assumptions.

2) Modeling

As part of the review of Monsanto's initial IRM plan for MON 89034, BPPD identified the need for additional species-specific (e.g, ECB and SWCB for the Corn Belt), spatially-explicit, landscape modeling to explore the durability of MON 89034 versus single-protein Bt corn products (BPPD 2007). Previously, Monsanto had cited the modeling work of Roush (1998) to demonstrate that a 5% refuge was justified with a two toxin pyramided product. Roush's model has a number of key assumptions, particularly

in terms of the toxin expression level in pyramided product. For homozygote susceptible insects, the model assumes 95% mortality and 70% mortality for heterozygotes (with one resistance allele) for each toxin. However, the dose information provided by Monsanto for MON 89034 was not sufficient to demonstrate that each protein would kill 95% of the homozygous susceptible insects and 70% of the heterozygotes (see BPPD 2007). BPPD recommended that Monsanto further characterize the dose expression for the MON 89034 toxins for the major target pests of the Corn Belt (ECB and SWCB). Given the dose uncertainties, BPPD could not at the time of registration support the use of Roush's model to justify a lower 5% refuge for MON 89034 (BPPD 2007).

Rather than re-run dose studies for Cry1A.105 or Cry2Ab2, Monsanto created a deterministic model for ECB and SWCB using dose mortality estimates consistent with the previously conducted studies. The model (Gustafson and Head 2008; contained in MRID# 474748-01) included the toxins from other registered Bt corn products (Cry1Ab, Cry1F) and has a number of assumptions and parameters:

- Dose mortality for ECB: 99.9% for Cry1 (Cry1Ab, Cry1F, Cry1A.105) and Cry2Ab2 toxins (one mortality scenario was modeled);
- Dose mortality for SWCB: 99 - 99.5% for Cry1 and 85 - 95% for Cry2Ab2 (six dose mortality scenarios were modeled);
- Complete resistance to Cry2Ab2 and Cry1A.105 (i.e. survival probability of heterozygote resistant individuals = 1) with no fitness costs;
- Heterozygotes (i.e. with one resistance allele) survival probability is twice that for homozygote susceptible insects;
- Three cross resistance scenarios: 1) Cry1A.105 and Cry1Ab fully cross resistant (but not Cry1F) (the "base case" scenario); 2) Cry1A.105 and Cry1F fully cross resistant (but not Cry1Ab) (alternate "base case" scenario), and 3) Cry1A.105, Cry1Ab, and Cry1F all fully cross resistant (worst case scenario);
- All resistance alleles (Cry1, Cry1A.105, and Cry2Ab2) have initial frequencies of 0.005. Cry1Ab and Cry1F are modeled as one output (i.e. estimated time to resistance for Yieldgard/Herculex);
- MON 89034 was assumed to have a refuge of 5%; other single gene products (Yieldgard and Herculex) were assumed to have 20% refuge;
- ECB and SWCB have no natural refuge (i.e. wild hosts or other cultivated crops that could serve as a source of susceptible insects) and have two generations per year on corn;
- A range of market share adoption values for MON 89034 and other products (Herculex and Yieldgard) were included in the model simulations. MKT 1 = 100% MON 89034; MKT 2 = 50% MON 89034, 25% MON 810, 25% TC1507; MKT 3 = 0% MON 89034, 50% MON 810, 50% TC1507.

Most of the assumptions above are conservative estimates, with the possible exception of the dose mortality parameters for SWCB (see discussion in the BPPD review section). Simulations were run with both ECB and SWCB to estimate the time to resistance (in years; up to a maximum of 30 years) and resistance allele frequency for each of the three cross resistance scenarios described above. Within each cross resistance scenario, model

runs were conducted for three different market adoption contingencies of MON 89034, MON 810 (Cry1Ab Yieldgard) and TC1507 (Cry1F Herculex).

ECB Results

For ECB, the results of the model runs were relatively consistent among the different cross resistance and market adoption scenarios. In almost all cases, the durability of the MON 89034 toxins (Cry1A.105 and Cry2Ab2; assuming a 5% refuge) exceeded the 30 year time frame of the model. Only in the "worst case" cross resistance scenario (i.e., all three toxins cross resistant) was the durability of Cry1A.105 less than 30 years (29 years) for ECB -- Cry2Ab2 remained effective in all model simulations (> 30 years). For the other Cry1 toxins (Cry1Ab and Cry1F) that are expressed in other Bt corn products, resistance developed in less than 30 years for some of the cross resistance and market adoption scenarios. In the "base case" (Cry1Ab and Cry1A.105 cross resistant), the durability of Cry1Ab/Cry1F lasted 26 years (0% MON 89034, 50% MON 810, 50% TC1507) and 29 years (50% MON 89034, 25% MON 810, 25% TC1507). However, for the alternate base case (Cry1F and Cry1A.105 cross resistance), resistance to Cry1Ab/Cry1F did not evolve within 30 years. In the worst case scenario (all three toxins cross resistant), resistance to Cry1Ab/Cry1F developed in 29 years.

SWCB Results

For SWCB, more model simulations were run to account for a range of dose mortalities. Overall, durability of the traits was affected by the dose mortality scenarios -- the simulations with lower dose mortality frequently resulted in fewer years to resistance in Cry1A.105 and Cry1F than those with higher dose mortalities. As with ECB, Cry2Ab2 remained durable (> 30 years) in all but one of the simulations regardless of the cross resistance or market adoption scenario.

For the "base case" cross resistance scenario, the time to resistance was lowest in the market adoption scheme (MKT 3) without MON 89034 (50% MON 810, 50% TC1507) ranging from 17 years (lower dose mortalities for Cry1 and Cry2Ab2 toxins) to 20.5 years (higher dose mortalities). Once MON 89034 was added to the model (MKT 1 and 2), the time to resistance with the Cry1 toxins increased by 2 -2.5 years for all simulations. Cry1A.105 and Cry2Ab2 did not evolve resistance in any of the model runs for MKT 2, although there were two instances with MKT 1 (100% MON 89034) in which resistance evolved within 30 years. In both of these cases, lower dose mortality values for SWCB (85% for Cry2Ab2; 99% for Cry1A.105) were included in the model.

Time to resistance in the "alternate base case" (Cry1F and Cry1A.105 cross resistant) was > 30 years in almost all cases. Only in the simulation that incorporated the lowest dose mortality values (85% for Cry2Ab2 and 99% for Cry1A.105) did resistance evolve to one of the toxins (28.5 years for Cry1A.105).

In the "worst case" (Cry1Ab, Cry1F and Cry1A.105 are all cross resistant), resistance developed in all scenarios for both the Cry1 toxins and Cry1A.105. Conversely,

Cry2Ab2 remained durable (> 30 years) for all of the simulations. Time to resistance in the Cry1 and Cry1A.105 toxins was lowest (17 years) in the model run using the lower SWCB dose mortality values (85% for Cry2Ab2 and 99% for Cry1A.105). Resistance also evolved for case with the higher dose mortality values, ranging up to 22 years for each toxin. A truncated summary of the results for all of the model simulations is contained in Table 2 below -- the complete results of the modeling are detailed in Tables 5 and 6 in Monsanto's submission (MRID# 474748-01).

Table 2: Results of Monsanto's model simulations of MON 89034 (5% refuge), MON 810, TC1507 (20% refuge) expressed in years to resistance (30 year maximum). Derived from data reported in MRID# 474748-01.

Pest		Cross resistance scenario				
		Base case[1]			Alt. base case[2]	Worst case[3]
		MKT 1	MKT 2	MKT 3		
ECB	Cry1A.105	>30	>30	N/A	>30	29
	Cry2Ab2	>30	>30	N/A	>30	>30
	Cry1Ab/Cry1F	N/A	29	26	>30	29
SWCB	Cry1A.105	22.5 - >30	>30	N/A	28.5 - >30	17 - 22
	Cry2Ab2	25 - >30	>30	N/A	>30	>30
	Cry1Ab/Cry1F	N/A	19 - 23	17 - 20.5	>30	17 - 22

[1] Base case = Cry1Ab and Cry1A.105 cross resistant; three different marketing scenarios included (Mkt 1 = 100% MON 89034, 0% MON 810/TC1507; Mkt 2 = 50% MON 89034, 25/25% MON 810/TC1507; Mkt 3 = 0% MON 89034, 50/50% MON 810/TC1507).
[2] Alt. base case = Cry1F and Cry1A.105 cross resistant (only Mkt 2 simulated).
[3] Worst case = Cry1A.105, Cry1Ab, and Cry1F all fully cross resistant (only Mkt 2 simulated).

Based on the model work, Monsanto concluded that the durability of the MON 89034 proteins (Cry1A.105 and Cry2Ab2) will remain strong for both ECB and SWCB. With a 5% refuge, Monsanto predicts that MON 89034 will have at least 22 years durability even under the "worst case" model assumptions. The durability of Cry2Ab2 in the model was particularly robust in almost all simulations for ECB and SWCB (only one simulation predicted less than 30 years durability). Resistance to Cry1A.105 was also rare in most simulations, although the "worst case" modeling (assuming complete cross resistance with Cry1Ab and Cry1F) showed resistance developing in less than 30 years. Monsanto also noted that in the simulations with different market adoption scenarios, the addition of MON 89034 increased the time to resistance for the previously registered Cry1 toxins (Cry1Ab and Cry1F).

BPPD Review - Modeling

BPPD agrees with Monsanto's overall conclusions that the model simulations demonstrate the effectiveness in delaying resistance of MON 89034 and provide support for the use of a 5% refuge in the Corn Belt. However, BPPD notes that some of the parameters and assumptions of the model could be revised to improve and expand the overall analysis.

For ECB, the model clearly predicts that resistance is unlikely to evolve to Cry1A.105, Cry2Ab2, or the previously-registered Cry1 toxins. Even under the worst case scenario that assumed complete cross resistance, the durability of all toxins was at least 29 years. Presumably, a large reason for this is the high dose mortality of the MON 89034 toxins against ECB. Previous mortality studies submitted by Monsanto (reviewed in BPPD 2007) showed that the Cry1A.105 and Cry2Ab2 proteins in MON 89034 each provide essentially 100% control of ECB (Monsanto assumed 99.9% mortality for each toxin in the model).

For SWCB, the model predictions were more varied, largely due to the different simulations run with the range of dose mortality assumptions. Not surprisingly, the simulations that were run with the lower mortality estimates (i.e. 85% for Cry2Ab and/or 99.0% for Cry1) resulted in less time to resistance than those using the higher dose values. In the worst case simulations with the lower dose estimates, SWCB resistance evolved in 17 years to both Cry1A.105 and Cry1Ab/Cry1F while with the higher doses resistance took 21 or 22 years to develop. As with ECB, Cry2Ab2 remained durable (>30 years) for almost all of the simulations.

A number of factors appeared to influence the model results. BPPD agrees with Monsanto that the addition of MON 89034 in the simulations testing various market adoption scenarios delayed resistance in the other previously-registered Cry1 toxins. Likely, these results were due to less selection pressure on each individual toxin because of a diverse mosaic of toxins in the landscape. Cross resistance was also an important variable. Monsanto's "base case" for cross resistance assumed cross resistance between Cry1Ab and Cry1A.105. This resulted in resistance always developing in Cry1Ab/Cry1F (i.e. within 30 years), although Cry1A.105 and Cry2Ab2 durability remained strong. On the other hand, when cross resistance between Cry1A.105 and Cry1F was assumed, resistance rarely developed in either the MON 89034 toxins or the existing Cry1 toxins. In the worst case scenario (all three toxins cross resistant), the durability of Cry1A.105 to SWCB was clearly impacted relative to the other cross resistance simulations. Conversely, Cry2Ab remained durable in almost all cases regardless of the varying assumptions and scenarios included in the model. Since Cry2Ab is not cross resistant to the Cry1 toxins, this result was not unexpected.

BPPD generally agrees with Monsanto that conservative assumptions were used in the model. However, BPPD notes that several of the parameters could have been expanded or have included an additional degree of conservatism or additional refinement to improve the model analysis. For example, Monsanto's simulations assumed a 5% refuge for MON 89034 (while maintaining the 20% refuge for the other Bt toxins). Although MON 89034 is currently registered with a requirement for a 20% refuge, simulations were not run with the larger refuge size. Separate simulations with 5% and 20% MON 89034 refuges would have been useful for comparative purposes. To illustrate using the SWCB "base case" (with the three different marketing adoption cases), with no MON 89034 adoption resistance to the Cry1 toxins occurred in 17 - 20.5 years. When MON 89034 with a 5% refuge was included, the time to Cry1 resistance was 19 - 23 years --

indicating that the addition of MON 89034 provides some delay in resistance development (2 - 2.5 years). It would have been interesting to observe the impact of adoption of MON 89034 with a 20% refuge on Cry1 resistance. In all likelihood, the time to resistance would be increased, although the magnitude of such an increase is unknown. Had the difference been small, it could be argued that there is little value gained in having a 20% refuge versus a 5% refuge.

The model time frame (maximum 30 years) was another limiting parameter. Many of the simulations resulted in no resistance within the 30 year time period of the model, so it was difficult to discern the effects of certain variables (i.e. cross resistance, market adoption, dose mortality) between model runs. Had the time horizon been extended (e.g. to 50 years), differences between the various model scenarios may have been apparent.

For the SWCB simulations, Monsanto used dose mortality range of 85-95% for Cry2Ab2 and 99-99.5% for Cry1 toxins. Based on the dose data submitted for the registration of MON 89034 (reviewed in BPPD 2007), BPPD believes these estimates to be somewhat high. For example, dose data for Cry2Ab2 and SWCB suggested a mortality range of 80-90%. The Cry1A.105 protein in MON 89034 provided approximately 95% control in mortality assays, though the other registered Cry1 proteins (Cry1Ab and Cry1F) may provide closer to 99% of SWCB. Had the model simulations been run with these more conservative dose estimates, it is likely the time to resistance would have been reduced in some scenarios. The extent of this effect is unknown, although BPPD notes that the differences between the lower Cry2Ab2 dose (85%) and the highest dose (95%) in the range appeared to be negligible in the model runs (i.e. no differences in years to resistance).

BPPD Review - Overall Proposal to Reduce Refuge

Taken together, Monsanto's cross resistance and modeling work provides justification for reducing the MON 89034 structured refuge requirement in the Corn Belt from 20% to 5% non-Bt corn. Key elements of support include a lack of cross resistance between Cry2Ab2 and Cry1 proteins and model simulations which demonstrate strong durability of Cry1A.105 and Cry2Ab2 under a variety of dose, market adoption, and cross resistance scenarios. Reducing the refuge to 5% is unlikely to increase the selection pressure for resistance in either MON 89034 or the other previously-registered Cry1Ab or Cry1F corn hybrids.

Despite a good case for a refuge reduction, BPPD notes that there are still some limitations and uncertainties in the analysis that could be addressed to provide additional support for the proposal. These areas include:

- Cross resistance between Cry1Ac and Cry1A.105. Cry1Ac is registered in Bt cotton products and the chimeric protein Cry1A.105 has two Cry1Ac domains. CEW feed on both corn and cotton and successive generations may have exposure to both Cry1A.105 and Cry1Ac during the same growing season;

- No model simulations were conducted to compare 5% vs. 20% refuge for MON 89034; the model assumed a 5% refuge for MON 89034;
- The model time horizon was limited to 30 years. Many of the model runs did not evolve resistance during this time precluding comparisons between some of the scenarios;
- SWCB model simulations included dose mortality estimates somewhat higher than those suggested by previously-submitted data. For Cry2Ab2, mortality ranged from 80 to 90% in dose testing submitted for MON 89034 (instead of 85-95% used in the model). Cry1A.105 caused 95% mortality in submitted dose studies, though a range of 99-99.5% was used in the model.

As a condition of registration of MON 89034, Monsanto was required to address cross resistance in existing Bt corn and Bt cotton products for Cry1A.105, Cry1Fa and Cry1Ac. Monsanto has sufficiently addressed cross resistance for Cry1A.105 and Cry1Fa, but there are lingering questions regarding Cry1Ac and Cry1A.105. The amendment submission included only a circumstantial discussion of Cry1Ac cross resistance with an assumption that the protein will behave similarly to Cry1Ab. However, since Cry1A.105 contains domains I and II and the C-terminal from Cry1Ac, BPPD is still concemed about the potential for cross resistance. As such, BPPD recommends additional work (as described in the cross resistance section above) to satisfy the condition of registration. Should additional cross resistance work (as previously described) demonstrate little or no cross resistance potential between Cry1A.105 and Cry1Ac, further support could be provided for the use of a 5% refuge in the Corn Belt.

In terms of resistance risk for MON 89034, cross resistance between Cry1Ac and Cry1A.105 is an issue primarily for CEW. This insect is known to feed on both corn and cotton during the same growing season and could be exposed to Cry1A.105 (in corn) and then Cry1Ac (in Bollgard cotton) later in the growing season. Theoretically, CEW could develop resistance to Cry1Ac due to exposure in cotton -- should there be a degree of cross resistance between Cry1Ac and Cry1A.105, MON 89034 could functionally have only Cry2Ab2 remaining as an effective toxin against CEW. With a reduced refuge (5%), selection pressure could be increased for resistance to MON 89034 and Cry2Ab2 (which also is expressed in Bollgard II cotton). While these are legitimate concerns (and reason for additional analysis), BPPD notes that there are several mitigating factors that reduce the overall resistance risk for CEW and MON 89034. First, CEW is generally a lesser pest in the Corn Belt than ECB (and in some areas SWCB), primarily due to poor overwintering capability in much of the Corn Belt (i.e. north of Virginia, Tennessee, and Missouri). Therefore, selection pressure for resistance will likely be less for CEW than ECB which does overwinter in the Corn Belt. On the other hand, in cotton-growing regions south of the Corn Belt where CEW can overwinter, conditions for resistance development may be more probable. In these areas, a 20% refuge (approved with the initial registration of MON 89034) will still be required. Along these lines, in Monsanto's original MON 89034 IRM submission, modeling was conducted to support the use of a 20% refuge for CEW in southern cotton-growing regions (see discussion in BPPD 2007).

A second mitigating factor is that CEW is a highly polyphagous insect and is known to feed on a wide variety of plants including weeds, wild hosts, and other cultivated crops (unlike ECB and SWCB which feed primarily on corn). Analysis conducted for Bollgard II cotton determined that a natural refuge is present for CEW (CBW) in cotton growing areas in the southeastern U.S. (see BPPD 2004 and 2006). It is likely that in the Corn Belt, there is also at least some degree of natural refuge that could supplement a 5% structured refuge to help reduce the overall selection pressure on CEW and MON 89034. BPPD emphasizes that natural refuge for CEW has been quantified only in cotton-growing regions and that host utilization patterns in the Corn Belt are speculative.

The other modeling parameter uncertainties detailed above are relatively minor, though a more expanded model analysis could have provided stronger support for the proposal. Separate model runs with 5% and 20% MON 89034 refuges would have been useful to compare potential differences in times to resistance. Although since most of the simulations did not result in resistance within 30 years, any differences would have been difficult to detect. Expanding the time horizon of the model (e.g. from 30 years to 60 years) possibly could have fleshed out variation between model scenarios and provided a more thorough basis for comparison. Finally, BPPD would have preferred if Monsanto had used the more conservative estimates of SWCB dose mortality (based on the MON 89034 dose data), though the impact on the model output would likely have been relatively small.

MON 89034 is an expiring registration (expiration date: September 30, 2010) and BPPD recommends reevaluating 5% refuge if warranted by cross resistance data or other information during this interim period.

References

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Gustafson, D. I. and Head, G.P., 2008. Modeling the Impact of a Five-Percent Structured Refuge on the Evolution of European and Southwestern Corn Borer Resistance to MON 89034 Corn. Report submitted to EPA by Monsanto. Contained in MRID# 474748-01.

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Moar, W., Roush, R., Shelton, A., Ferre, J., MacIntosh, S., Leonard, B.R., and Abel, C., 2008. Field Evolved Resistance to Bt Toxins. Nature Biotechnology 26: 1072-1074.

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Tabashnik, B.E., 1994. Evolution of resistance to *Bacillus thuringiensis*. Annu. Rev. Entomol. 39: 47-79.

Tabashnik, B.E., Gassmann, A.J., Crowder, D.W., and Carriere, Y., 2008. Insect resistance to Bt crops: evidence versus theory. Nature Biotechnology 26: 199-202.

Jeannine
Kausch/DC/USEPA/US
10/24/2008 01:59 PM

To "SCHNEIDER, RUSSELL P [AG/1920[" <russell.p.schneider@monsanto.com>
cc Mike Mendelsohn/DC/USEPA/US@EPA
bcc
Subject Re: approval letter

Hi Mr. Schneider,

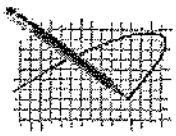
The data submitted for the refuge amendment for MON 89034 and MON 89034 x MON 88017 are still in review. I believe the primary review is actually complete and that the primary review is being peer-reviewed; therefore, because nothing has been formally completed yet, I can not give you a final determination from the IRM team. However, as soon as the peer review is complete and I've discussed the conclusions with the IRM team, I will get back to you.

Thanks for your inquiry,

Jeannine Kausch

Environmental Protection Specialist
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
(703) 347-8920 (telephone)
(703) 305-0118 (fax)

Mike Mendelsohn/DC/USEPA/US



Mike
Mendelsohn/DC/USEPA/US
10/24/2008 01:47 PM

To "SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>
cc Jeannine Kausch/DC/USEPA/US@EPA
Subject Re: approval letter

Russ,

The detail is going well and I am learning much from USDA. Thanks for asking. The refuge amendment is being managed by Jeannine Kausch. I suggest you contact her about the status.

Best Regards,

Mike Mendelsohn
Senior Regulatory Specialist
Office of Pesticide Programs/ Biopesticides and Pollution
Prevention Division (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460
(703) 308-8715
(703) 308-7026 (fax)
http://www.epa.gov/pesticides/biopesticides
"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>

DATA PACKAGE BEAN SHEET

Date: 09-Dec-2008

Decision #: 400603
DP #: (357201)
NON PRIA
Parent DP #:
Submission #: 837684

* * * Registration Information * * *

Registration: 524-575 - MON 89034

Company: 524 - MONSANTO COMPANY

Risk Manager: RM 92 - Dennis Szuhay - (703) 305-6098 Room# PY1 S-8761

Risk Manager Reviewer: Jeannine Kausch JKAUSCH

Sent Date: _____ Calculated Due Date: 25-Jan-2009 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (575) CONDITIONAL REGISTRATION FOLLOW-UP;DATA REQUIRED;REQUIRES SCIENCE

Ingredients: 006515, Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-

006514, Bacillus thuringiensis Cry1A.105 protein and genetic material necessary (vector PV-ZMIR245) for its production in

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 09-Oct-2008 Due Back: _____

DP Ingredient: 006514, Bacillus thuringiensis Cry1A.105 protein and genetic material necessary (vector PV-ZM

006515, Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-

DP Title: Bt Corn IRM CAP - ABSTC

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #: _____

	Assigned To	Date In	Date Out		
Organization:	BPPD / MPB	04-Dec-2008		Last Possible Science Due Date:	03-Nov-2008
Team Name:	MPB IRM Science Review	04-Dec-2008		Science Due Date:	
Reviewer Name:	Borges, Shannon	04-Dec-2008		Sub Data Package Due Date:	
Contractor Name:					

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Printed on Page 2

* * * Data Package Instructions * * *

Hi Shannon,

As a condition of registration, Monsanto was told to submit a written description of their compliance assurance program for MON 89034. Included in this submission are the compliance assurance program with some revisions (indicated in the cover letter), as well as a technology use guide.

Please review to ensure that both of these components are acceptable and satisy the relevant condition of registration.

Thanks,

Jeannine

DP#: (357201) *** Additional Data Package for this Decision *** Decision#: (400603)

DP #	Division/Branch	Date Sent	Date Due	Instructions?	CSF	label
357200	BPPD / MPB	09-Oct-2008	03-Nov-2008	○ Yes ○ No	○ Yes ● No	○ Yes ● No
357200	BPPD / MPB	09-Oct-2008	03-Nov-2008	○ Yes ○ No	○ Yes ● No	○ Yes ● No

DATA PACKAGE BEAN SHEET

Date: 09-Dec-2008

Decision #: 400603
DP #: (357200)
NON PRIA
Parent DP #:
Submission #: 836964

* * * Registration Information * * *

Registration: 524-575 - MON 89034

Company: 524 - MONSANTO COMPANY

Risk Manager: RM 92 - Dennis Szuhay - (703) 305-6098 Room# PY1 S-8761

Risk Manager Reviewer: Jeannine Kausch JKAUSCH

Sent Date: 29-Sep-2008 Calculated Due Date: 12-Jan-2009 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (575) CONDITIONAL REGISTRATION FOLLOW-UP;DATA REQUIRED;REQUIRES SCIENCE

Ingredients: 006515, Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-

0065t4, Bacillus thuringiensis CrytA.t05 protein and genetic material necessary (vector PV-ZMIR245) for its production ir

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 09-Oct-2008 Due Back:

DP Ingredient: 006514, Bacillus thuringiensis CrytA.t05 protein and genetic material necessary (vector PV-ZM

0065t5, Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-

DP Title: Response to conditions of registration

CSF Included: ◯ Yes ● No Label Included: ◯ Yes ● No Parent DP #:

Assigned To		Date In	Date Out		
Organization:	BPPD / MPB	04-Dec-2008		Last Possible Science Due Date:	03-Nov-2008
Team Name:	MPB IRM Science Review	04-Dec-2008		Science Due Date:	
Reviewer Name:	Borges, Shannon	04-Dec-2008		Sub Data Package Due Date:	
Contractor Name:					

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Printed on Page 2

* * * Data Package Instructions * * *

Hi Shannon,

As a condition of registration, Monsanto was told to submit a written description of their compliance assurance program for MON 89034 . Included in this submission are the compliance assurance program with some revisions (indicated in the cover letter), as well as a technology use guide.

Please review to ensure that both of these components are acceptable and satisy the relevant condition of registration.

Thanks,

Jeannine

DP#: (357200) *** Additional Data Package for this Decision *** Decision#: (400603)

DP #	Division/Branch	Date Sent	Date Due	Instructions?	CSF	label
357201	BPPD / MPB	09-Oct-2008	03-Nov-2008	○ Yes ○ No	○ Yes ● No	○ Yes ● No
357201	BPPD / MPB	09-Oct-2008	03-Nov-2008	○ Yes ○ No	○ Yes ● No	○ Yes ● No

MONSANTO
imagine

MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST LOUIS, MISSOURI 63167
http://www.monsanto.com

October 6, 2008

Ms Jeannine Kausch
Biopesticides and Pollution Prevention Division Office of Pesticide Programs
United States Environmental Protection Agency
Washington, DC 20460

Subject: Conditions of Registration for MON 89034 (EPA Reg No. 524-573) and MON 89034 x MON 88017 (EPA Reg No. 524-576)

Dear Ms Kausch:

In response to your request (e-mail on October 3, 2008), we are providing the following two documents:

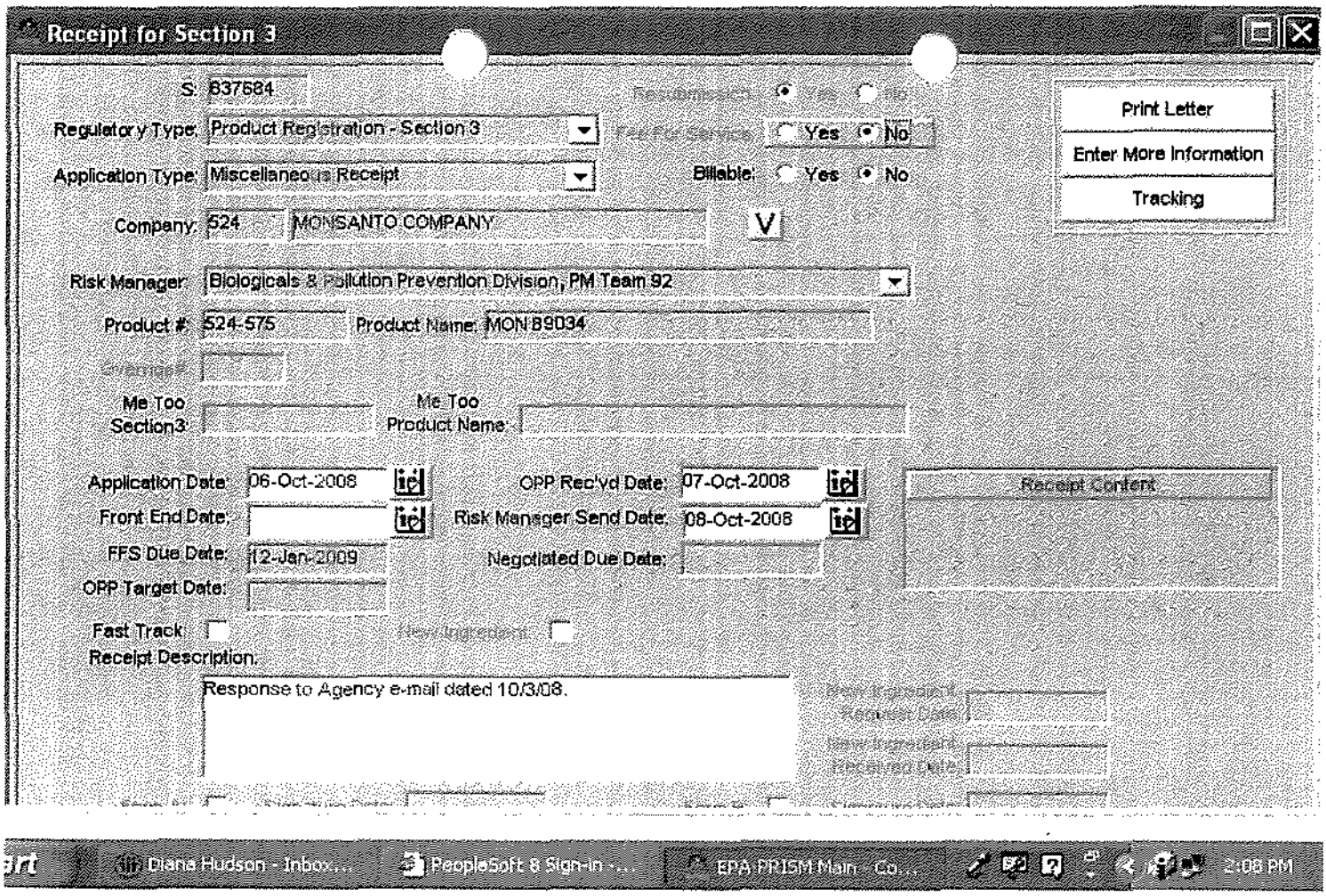
1. "Bt Corn IRM Compliance Assurance Program" developed by the Agricultural Biotechnology Stewardship Technical Committee (dated September 23, 2002)
2. "Revised IRM Compliance Assurance Program for Corn Event MON 863" developed by Monsanto, and approved by the EPA on August 11, 2006 for use in MON 88017 compliance assurance program

If you have any questions regarding this correspondence please feel free to contact Dr. Russell Schneider, Senior Director, Monsanto Regulatory Affairs and Policy at (202) 383-2866, or me at (314) 694-2943 or yong.gao@monsanto.com.

Sincerely,

Yong Gao, Ph.D.
Regulatory Affairs Manager

cc: Russell Schneider, Monsanto
Carolyn Carrera, Monsanto



OCT 0 8 2008

D. 406603

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
File Symbol 524-575	Sheryl Reilly	☒ None ☐ Restricted
Company/Product (Name): MON 89034	PM #: 90	

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167
☐ Check if this is a new address

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section – II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification – Explain below.
☐ Final printed labels in response to Agency letter dated
☐ "Me Too" Application.
☒ Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Materials to support Compliance Assurance Program of MON 89034

Section – III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No		☐ Yes ☐ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other
* ***Certification must be submitted***	If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt.	No. per Container	*(Specify)*

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section – IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. *(Include Area Code)*
Russell P. Schneider	Sr. Director, Regulatory Affairs & Policy	(202) 383-2866

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title	4. Typed Name	5. Date
Yong Gao	Regulatory Affairs Manager	Yong Gao, Ph.D. Tel. (314) 694-2943	October 6, 2008

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Bt Corn IRM Compliance Assurance Program
ABSTC

September 23, 2002

1.0 Introduction

Adherence by growers to the Insect Resistance Management (IRM) requirements mandated by EPA is an important factor for preventing the development of resistance to Bt by key corn insect pests such as the European corn borer. Preserving the effectiveness of this technology will allow U.S. corn growers and consumers to continue to enjoy its economic and environmental benefits. Consequently, promoting compliance with IRM requirements is of overriding importance to both registrants and growers alike.

The registrants[1] of Bt corn products registered by EPA in October 2001 ("Bt Corn"), working through the Agricultural Biotechnology Stewardship Technical Committee ("ABSTC"), are implementing a multifaceted strategy for promoting grower compliance with the IRM requirements and reducing the probability for development of insect resistance, consistent with the terms and conditions of registration for those products. This multifaceted strategy includes a balance of proactive and remedial aspects. Proactive measures generally occur prior to planting and are designed to make growers aware of the need to comply with their IRM obligations. Remedial aspects of the overall IRM compliance strategy consist of measures that are taken when noncompliance with the IRM requirements is detected. These remedial measures are generally directed at bringing noncompliant growers into compliance with their IRM obligations; however, remedial measures can also include a registrant denying a noncompliant grower access to the registrant's Bt Corn technology. Some of the main components of this multifaceted IRM compliance strategy are highlighted below.

Grower Education

Grower education is the single most important element of any strategy for promoting compliance with the IRM requirements. Survey data have consistently shown that the vast majority of Bt Corn growers seek to comply with the IRM requirements when they are made aware of them. For example, a survey of Bt Corn growers conducted by an independent market research firm reveals that approximately 96% of Bt Corn growers planted a refuge in 2001.[2] Similar results were seen in a survey conducted in 2000.[3]

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[1] For purposes of this Compliance Assurance Program, discussion of the registrants' IRM compliance assurance efforts is intended to encompass agents of the registrants as well, which may include licensees, dealers, or others.

[2] *Bt Corn IRM Grower Survey* (January 2002), Marketing Horizons, Inc.

[3] The 2000 IRM Grower Survey revealed that over 90% of Bt Corn growers surveyed planted a refuge in 2000. *Bt Corn Insect Resistance Management Survey* (January 31, 2001), Marketing Horizons, Inc.

Survey results also indicate that grower compliance is positively correlated with the number of times a grower receives information about the IRM requirements.[4] These results underscore the central importance of grower education in a multifaceted IRM compliance strategy.

The Bt Corn registrants are engaging in an aggressive and broad-based educational campaign aimed at ensuring that Bt Corn growers understand their IRM obligations. This educational program encompasses extensive efforts that have been undertaken by the registrants individually, as well as coordinated efforts among the registrants and other stakeholders, such as the National Corn Growers Association (NCGA) and cooperative extension services. These educational efforts have included the following:

- The development, along with NCGA, of the Insect Resistance Management Fact Sheet for Bt Corn. Approximately 900,000 copies of this fact sheet have been printed and made available to seed company representatives, retailers, growers and others;

- The development, in cooperation with NCGA, of an IRM logo, which has been incorporated into a number of educational and sales materials;

- Training sales representatives on IRM principles and requirements;

- References to IRM in seed catalogs, seed bag tags, and promotional materials;

- Articles on IRM published in seed company magazines and websites;

- The distribution of news releases to, and the placement of educational materials in, farm media, informing growers of IRM requirements.

These continuing educational efforts are described in more detail in a comprehensive IRM Education Program, which each Bt Corn registrant has submitted to EPA in a separate document.

Grower Agreements

Grower Agreements (also referred to as "Technology Agreements" or "Stewardship Agreements") are another component of the overall IRM compliance strategy that EPA requires Bt Corn registrants to employ. These agreements impose legally binding contractual obligations on Bt Corn growers including the obligation to comply with all applicable IRM requirements. In order to obtain access to Bt Corn technology, growers are required to sign these agreements. In addition, each registrant is required to develop and implement a system that is reasonably likely to assure that all purchasers of Bt Corn seed have, in fact, signed a grower agreement as required. Each Bt Corn registrant has submitted a written description of this system to EPA in a separate document.

[4] *Bt Corn IRM Grower Survey* (January 2002), Marketing Horizons, Inc.

Annual Affirmation of IRM Obligations

Under the terms and conditions of registration, each Bt Corn registrant is required to develop and implement a system under which growers purchasing that registrant's Bt Corn products annually affirm their contractual obligation to comply with the IRM requirements. The annual affirmation is intended to reinforce with Bt Corn growers that they are contractually bound to comply with the IRM requirements. As required under the terms and conditions of registration, the Bt Corn registrants have provided EPA with a written description of their proposed annual affirmation system in a separate submission.

Another important component of the multifaceted approach to IRM compliance is the implementation of a Compliance Assurance Program by the Bt Corn registrants. Under the terms and conditions of registration established on October 15, 2001, each Bt Corn registrant must implement an ongoing IRM Compliance Assurance Program that is designed to (i) evaluate the extent to which growers of Bt Corn are complying with the IRM requirements; and (ii) take actions reasonably needed to assure that growers who have not complied with the IRM requirements are brought back into compliance with the IRM requirements. The remainder of this document describes in detail the IRM Compliance Assurance Program that will be implemented for Bt Corn beginning in 2002.[5]

2.0 The Compliance Assurance Program

As specifically provided for in the Bt Corn registrations, the Compliance Assurance Program is intended to allow for flexibility in the specific methods that are employed by the individual registrants to assure that Bt Corn growers satisfy their IRM obligations. This flexibility is needed to account for differences in the ways in which the registrants conduct business, as well as the different sets of compliance tools that are available to each registrant. In addition, flexibility is essential to an effective Compliance Assurance Program because it allows registrants to employ responses that are appropriately tailored to the particular circumstances surrounding individual instances of noncompliance, instead of being forced to utilize ineffectual one-size-fits-all approaches. It should also be noted that "flexibility" in the context of the Compliance Assurance Program applies to how the registrants implement and administer the IRM program – not the actual IRM requirements or the compliance standards employed across the industry. Bt Corn growers are subject to and must follow the same IRM requirements and will be subjected to consistent compliance standards regardless of the registrants and/or seed companies with whom they choose to do business.

[5] In addition, consistent with the terms and conditions of registration, each registrant has provided EPA with a separate document that describes the compliance assurance activities that were implemented by the registrant in 2001.

2.1 General Description of the Compliance Assurance Program

The terms and conditions of registration of Bt Corn that were established on October 15, 2001 indicate that the Compliance Assurance Program must perform two functions: (i) it must provide a mechanism for evaluating the extent of IRM compliance among Bt Corn growers, and (ii) it must provide a mechanism for responding to instances of noncompliance in a manner that brings noncompliant growers back into compliance with the IRM requirements. In particular, the terms and conditions of registration specify that the Compliance Assurance Program must contain the following four elements:

- **An Annual IRM Survey** The registrants are required to sponsor an annual survey of a statistically representative sample of Bt Corn growers, to be conducted by an independent third party. The survey is required to measure the degree of adherence to IRM requirements among growers in different regions of the United States, and must be designed to provide an understanding of the reasons, extent, and potential biological significance of any implementation deviations. In addition, the survey must be designed to obtain grower feedback on the usefulness of specific educational tools and approaches.

- **A Mechanism for Handling Tips and Complaints** Each registrant must implement a program for investigating "legitimate tips and complaints" about growers who may be out of compliance with their IRM obligations.

- **Training of Seed Company Representatives** Seed company representatives who make on-farm calls are required to be trained to assess grower adherence to IRM requirements. Instances of growers failing to meet the IRM requirements that are detected through such on-farm calls are to be addressed in a manner consistent with the registrants' "phased compliance approach."

- **A Phased Compliance Approach** The registrants must establish and publicize a phased compliance approach describing how instances of noncompliance with IRM requirements will be addressed, and the general criteria that will be applied in choosing among options for responding to noncompliance. The Bt Corn registrants are directed to use a consistent set of standards for responding to noncompliance.

Each of these elements of the Bt Corn IRM Compliance Assurance Program is separately addressed in the sections that follow.

2.2 The IRM Survey

The annual registrant-sponsored IRM survey of Bt Corn growers is a key tool for monitoring overall grower adherence to the IRM requirements and the effectiveness of IRM educational efforts. It should be pointed out, however, that the purpose of the IRM survey is not to identify individual noncompliant growers.

In prior years, the Bt Corn registrants, working through ABSTC, sponsored a survey of Bt Corn growers that was jointly developed by an independent professional market research firm working with the registrants and other stakeholders. Going forward, the development and implementation of the annual survey will remain a transparent process. An independent, third-party professional market research firm will continue to be responsible for the design and conduct of the survey with input from academics and the Bt Corn registrants, as well as input and feedback from NCGA, EPA and USDA.

In conducting the survey, both an unaided and aided approach will continue to be used, to give a high degree of scientific rigor to the survey. This is a reliable method for obtaining valid information on grower implementation of IRM requirements and allows for sampling of Bt Corn growers across a wide geography in a short period of time. In addition, the survey design will incorporate the following features:

- The sample size will be chosen to allow for reasonable sensitivity in comparing results across the United States, and may be adjusted to allow for analysis and comparison of behavior among different regions of the country.

- The survey will be designed to allow for an assessment of the reasons, extent, and biological significance of deviations from the IRM requirements. This information will provide a better understanding of grower implementation of the IRM plan, and will be useful in determining how educational efforts should be focused and/or modified and whether modifications to the IRM Compliance Assurance Program are appropriate and feasible.

- The professional design of the survey minimizes the potential for false positives or nonresponse bias. The percentage of Bt Corn and field locations are determined prior to asking directly about refuges or mentioning IRM. Growers were apparently comfortable being asked questions about Bt Corn IRM since growers terminated only about one percent of interviews and this refusal rate is consistent with other agricultural product market research.

- The experience of the independent research firm conducting the research is that a telephone survey has advantages over other survey methods. A mail survey, for example, is more likely to introduce bias, as growers can review all the questions before deciding whether or not to answer and how to answer.

- If the results of the annual grower survey indicate that growers in a particular geographic region are not adhering to IRM requirements at a sufficiently high level, the registrants will take appropriate actions to increase awareness of the IRM requirements in that region through more aggressive grower education efforts. If, based on the results of the annual survey, the registrants conclude that modifications to the current Compliance Assurance Program may be warranted, those proposed modifications will be submitted to EPA in conjunction with the annual report on the survey results required under the terms and conditions of registration.

2.3 Investigation of Tips and Complaints

Each Bt Corn registrant will establish a system to collect and investigate legitimate tips and complaints regarding alleged instances of noncompliance with the IRM requirements. Information gathered through this system will complement the annual survey and will help to monitor compliance at the individual grower level. This system will consist of the following components:

- Tips and complaints received by a registrant will be evaluated to ascertain their legitimacy. In general, a tip or complaint will be deemed legitimate if the following three criteria are satisfied: (i) the person making the tip or complaint provides sufficient information for the registrant to contact such person; (ii) the tip or complaint identifies a specific grower as being out of compliance with the IRM requirements; and (iii) the tip or complaint provides some reasonable description of the nature of the violation or the basis for believing a violation has occurred.

- Recognizing that individuals may be reluctant to report potential instances of noncompliance if their identities are not protected, the registrants will take reasonable steps to assure persons submitting a tip or complaint that his or her identity will be maintained in confidence to the extent permitted by law.

- The registrants will investigate legitimate tips and complaints by contacting the grower who is alleged to be out of compliance. Each such contact shall be documented.

- If the investigation of a tip or complaint confirms that a grower is out of compliance with the IRM requirements, that noncompliance will be addressed in accordance with the "Phased Compliance Approach" described below. If, based on the investigation of a tip or complaint, the registrant concludes that a grower is not out of compliance, that conclusion will be documented.

2.4 Training of Company Representatives Making On-Farm Calls

As a part of the sales, servicing and stewardship of the Bt Corn products as well as other seed and agricultural products, the Bt registrants, their sales representatives, agronomists, dealers and others regularly make a significant number of routine on-farm calls at various times during the year. These on-farm calls will be a primary tool for determining individual grower adherence to the IRM requirements and identifying specific growers who are not fully meeting the requirements. Moreover, these on-farm calls may be used as follow-up on-farm "compliance assistance" and "compliance assessment" contacts and visits described in Section 2.5.2 which are intended to deal with a grower already identified as having had a deviation from the IRM requirements in the previous year. It should be clarified that on-farm visits are not intended to

validate the anonymous survey results as registrants will include individual growers suspected of being out of compliance for on-farm visits which would not produce a representative sample of grower noncompliance.

Company representatives, including those who may sell Bt Corn seed, currently receive training in the IRM requirements as part of their annual training. Starting in 2002, this training will be supplemented to cover the provisions of the IRM Compliance Assurance Program. In addition, starting in 2002, the registrants will begin to give specific training to company representatives who routinely make on-farm calls on how to identify growers who fail to meet the IRM requirements. This new training initiative will proceed in phases, as described below.

Commencing in 2002, each registrant will evaluate the effectiveness of possible methods by which company representatives might detect growers who fail to meet the IRM requirements. Such methods might, but need not necessarily, include: (i) invoice monitoring, or (ii) use of a verbal and/or written questionnaire administered to growers, or (iii) other methods. Based on its evaluation of the different possible detection methods, each registrant will select one or more methods to implement and will develop appropriate training materials for its representatives. In the latter part of 2002 or early part of 2003, company representatives who routinely make on-farm calls will be trained in the selected detection method(s).

2.5 Phased Compliance Approach

Under the terms and conditions of registration issued on October 15, 2001, the Bt Corn registrants are required to develop, implement and publicize a "Phased Compliance Approach." This Phased Compliance Approach articulates a common set of standards that will be applied by the registrants in responding to instances of grower noncompliance with the IRM requirements.

The Phased Compliance Approach is intended to provide a mechanism for responding to noncompliance in a manner such that noncompliant growers are brought back into compliance with the IRM requirements. In order to achieve this objective, the Phased Compliance Approach consists of a step-wise approach to responding to noncompliance. Under this approach, registrants will employ a variety of responses depending on the degree of significance of the noncompliance being addressed. Thus, significant deviations from the IRM requirements will be responded to with more intensive intervention than nonsignificant deviations.

Finally, the Phased Compliance Approach is intended to provide registrants with flexibility in choosing how they respond to noncompliance, in order to accommodate the specific circumstances of each particular instance of noncompliance and to allow the registrants to address the underlying reasons for the noncompliance, as well as the extent and biological significance of the noncompliance, using the particular tools that are available to each registrant. The specific details of the Phased Compliance Approach are described in more detail below.

2.5.1 Evaluating the Significance of NonCompliance

As explained above, under the Phased Compliance Approach, the response that is employed to address an instance of noncompliance will depend on the degree of significance of the

noncompliance. Any grower found not to be in full compliance with the IRM requirements would be visited in the subsequent year to evaluate if that grower is in compliance. Moreover, as defined in the terms and conditions of the Bt Corn registrations, "[a]n individual grower found to be ***significantly*** out of compliance two years in a row would be denied sales of the product the next year" by the registrant.

Either of the following types of noncompliance is deemed to constitute a ***significant deviation***:

- A Bt grower has planted less than a 15 percent (15%) non-Bt Corn refuge (except in certain cotton growing areas in which case it would be less than a forty percent (40%) non-Bt Corn refuge); or

- Fewer than two-thirds (2/3) of the Bt Corn fields are planted within one-half (½) mile of a non-Bt Corn refuge.

These types of noncompliance potentially pose a risk of contributing to insect resistance, particularly in areas of high Bt Corn penetration, and consequently, warrant aggressive responses focused on bringing the noncompliant grower back into compliance or, if significant noncompliance continues, denying the grower access to the Bt Corn product.

2.5.2 Responding to Instances of NonCompliance

Registrants may employ a number of different measures, of varying degrees of response, to instances of noncompliance. Under the Phased Compliance Approach, there are certain responsive measures on the part of the registrant that are mandatory, reflecting the minimum level of response appropriate for responding to noncompliance. There are additional responsive measures to be employed as deemed appropriate and necessary by the registrant. These additional responses are designed to allow registrants the ability to tailor their responses in a manner that best addresses the specific circumstances associated with a given instance of noncompliance, including, for example, the extent of the deviation from IRM requirements, the risk of contributing to insect resistance, and the extent to which the grower made a good faith effort to comply with the IRM requirements. Below are the mandatory and additional responses that may be employed.

Registrants will continue to provide IRM education and compliance monitoring during routine meetings, sales calls, conversations, presentations, on-farm calls, etc., between the registrants or their representatives and Bt Corn growers. In instances where growers are specifically identified as noncompliant with the IRM requirements, the appropriate registrant will contact the growers prior to the next growing season to provide "compliance assistance" and during the subsequent growing season to perform a "compliance assessment". "Compliance assistance" is intended to provide the grower with the assistance and instruction suitable to bring that grower into compliance with the IRM requirements. A "compliance assessment" is an after-planting assessment of the grower's actual activities to verify whether or not he or she is meeting the IRM requirements.

These compliance assistance and compliance assessment visits or contacts may be accomplished by various methods including on-farm face-to-face meetings, face-to-face off-farm meetings, conversations via the telephone, etc. Which particular method will be employed in a particular situation needs to be flexible and appropriate to the particular circumstances. These circumstances can include the individual grower's schedule and availability, the severity of the deviation, the availability of a trained representative to travel to the farm, the distance to the farm and/or distance to or between the fields at issue. As the registrants do not have unlimited resources, they must target their efforts and resources in a cost effective and appropriate manner. Additionally, while it may seem that an on-farm meeting is the most effective method of verifying adherence to IRM requirements, this is not necessarily true. As growers often have farming operations spread over one or more counties, individual field inspections may just not be feasible or practical. Moreover, even where field inspections are possible, the extent to which a grower has planted Bt Corn versus conventional corn is not apparent on visual examination. Short of doing actual bioassays on all the grower's corn, which is cost prohibitive and impractical, the best method for acquiring planting information is directly from the grower. Consequently, an appropriate discussion and/or series of questions is the key method for determining whether a grower is meeting the requirements, and this can occur just as readily in person on or off the farm or during a telephone conversation.

Responses to Significant Deviations

For ***significant deviations***, the MANDATORY responsive measures consist of the registrant taking ALL the actions described in items A through E below.

A. The grower who is identified as being out of compliance will receive a warning letter from the registrant, prior to the next growing season. The warning letter will: (i) remind the grower of his/her contractual obligation to comply with the IRM requirements; (ii) inform the grower that a significant deviation was detected and describe the steps needed to adhere to the IRM requirements; and (iii) remind the grower that if he/she is again found to be significantly out of compliance with the IRM requirements in the next growing season, he/she will be denied access to the Bt Corn product the following year.

B. The grower who is identified as being out of compliance will receive one or more "compliance assistance" contacts prior to planting the following season, in which a representative of the registrant will contact the grower to (i) remind the grower of his/her obligation to comply with the IRM requirements; (ii) inform the grower that a significant deviation was detected and describe the steps needed to adhere to the IRM requirements; and (iii) remind the grower that if he/she is again found to be significantly out of compliance with the IRM requirements in the next growing season, he/she will be denied access to the Bt Corn product the following year.

C. The noncompliant grower will be provided with additional IRM education to ensure that the grower is informed of his/her IRM obligations.

D. The noncompliant grower will receive a "compliance assessment" contact from a representative of the registrant the following growing season, in order to assess his/her adherence to the IRM requirements. This contact will be made in person.

E. Any grower that has been identified with a significant deviation in two consecutive seasons will be denied access to the Bt Corn product by the registrant for at least the following growing season.

Responses to Other Deviations

For ***other deviations*** that are near to but fall short of the IRM requirements, the MANDATORY responsive measures consist of the registrant taking the actions described in items A *and/or* B below, *and*, in all cases, the registrant taking the actions described in items C *and* D.

A. The grower who is identified as being out of compliance will receive a letter from the registrant that (i) reminds the grower of his/her obligation to comply with the IRM requirements; (ii) informs the grower that a deviation was detected; and (iii) informs the grower of the appropriate steps needed to adhere to the IRM requirements;

and/or

B. The grower who is identified as being out of compliance will receive one or more "compliance assistance" contacts prior to planting the following season, in which a representative of the registrant will contact the grower to (i) remind the grower of his/her obligation to comply with the IRM requirements; (ii) inform the grower that a deviation that was detected; and (iii) inform the grower of the appropriate steps needed to adhere to the IRM requirements.

And in all cases:

C. The noncompliant grower will be provided with additional IRM education to ensure that the grower is informed of his/her IRM obligations.

D. The noncompliant grower will receive a "compliance assessment" contact from a representative of the registrant the following growing season, in order to assess the grower's compliance with the IRM requirements.

The ADDITIONAL measures that may be employed in response to ***significant or other deviations,*** as dictated by the circumstances, consist of one or more of the following:

- **Invoice Monitoring.** The registrant may initiate monitoring of the noncompliant grower's future seed purchases in an effort to determine whether the grower purchases an amount of non-Bt Corn seed appropriate for the required refuge size. For example, if a grower is located in an area where a 20% non-Bt Corn refuge is required, and invoice monitoring reveals that 85% of the seed purchased by the grower is Bt Corn seed, then a flag would be triggered to signal that the grower may not have purchased enough non-Bt Corn seed to satisfy the applicable refuge

requirement. A grower that is flagged in this manner would be reminded of his/her IRM obligations.[6]

- **Technical Assistance.** The registrant may offer the noncompliant grower specialized technical assistance (for example, from an agronomist), to address particular difficulties that may have caused or contributed to noncompliance.

- **Grower Training.** The noncompliant grower may be required to receive additional training in IRM compliance prior to being allowed to purchase additional quantities of Bt Corn seed from the registrant.

- **Reaffirmation of IRM Obligations.** The noncompliant grower may be required to sign a new grower agreement or to otherwise reaffirm his/her contractual obligations to comply with the IRM requirements prior to being allowed to purchase additional quantities of Bt Corn seed.

- **Denial of Access to the Bt Corn Product.** The registrant may elect to deny access to the Bt Corn product to a grower who repeatedly fails to comply with the IRM requirements.

Responses to Repeated NonCompliance by a Grower

As required by the terms and conditions of the Bt Corn registrations, the registrant will visit growers found not to be in full compliance with the IRM requirements. In instances where a grower has had ***significant deviations*** in two consecutive growing seasons the grower will be denied access to Bt Corn seed by the registrant for at least the year following the consecutive year of noncompliance. The registrant may also implement any of the optional responses discussed previously. In addition, each registrant maintains the right, in accordance with their contractual agreement with the grower, to deny access to the Bt Corn product to any grower who repeatedly fails to comply with the IRM requirements. For example, if a grower plants a 15 percent refuge year after year, the registrant may deny access to the Bt Corn product to emphasize the importance of fully adhering to the IRM requirements.

The various responses that are available for noncompliance with the IRM requirements are summarized in a table included as Attachment 1 to this Compliance Assurance Program.

2.5.3 Responding to Grower NonCompliance in a Geographic Area.

If an inordinate number of growers in a specific geographic area are not complying with the IRM requirements, the registrant may suspend access to its Bt Corn for all the growers in that area. While one shortfall of this approach is that it potentially punishes compliant growers in the area

[6] It should be noted that a grower whose invoices indicate purchases of greater than 80% Bt Corn seed is not necessarily out of compliance, since, for example, the grower could purchase non-Bt refuge seed from another seed company or from the same seed company at a later date.

and could deprive them of access to an important agricultural technology, in extreme situations, it may be the appropriate response for dealing with widespread and repeated noncompliance in a geographic area.

2.5.4 Responding to Seed Dealers Not Fulfilling their IRM Obligations

If a registrant receives credible information that a seed dealer is not fulfilling his/her obligations to educate growers of their IRM obligations, the registrant will conduct a follow-up investigation to verify such information. If as a result of its investigation, the registrant determines that the seed dealer has failed to fulfill such IRM grower education obligations, the registrant will take appropriate actions to bring the dealer into compliance with those obligations. If the seed dealer is not fulfilling his/her IRM grower education obligations within a reasonable period of time, the registrant will suspend the dealer's authority to sell Bt Corn seed for one or more growing seasons.[7]

2.5.5 Publicizing the Phased Compliance Approach

The registrants will provide information regarding the key elements of the Phased Compliance Approach to growers, seed dealers and sales representatives. This information may, but need not necessarily, be incorporated into the IRM educational materials that are distributed by the registrants. It is not anticipated that the registrants will publicize the level of deviation considered "significant" since this may communicate the wrong message to growers that full compliance is not required. Instead, the information publicized should emphasize how to comply with the IRM requirements, the importance of compliance, the fact that random on-farm assessments of compliance will take place, and the consequences of repeated noncompliance, i.e., the real potential for a grower to lose access to the technology.

3. Conclusion

The Compliance Assurance Program is in many respects an innovative and unprecedented way to achieve grower compliance with regulatory requirements. For this reason, it was designed to allow flexibility to the individual registrants to facilitate their implementation and administration of the program. It also is intended to be somewhat dynamic in character, and the terms of the October 15, 2001 registrations specifically provide that "annually, the registrant shall revise, and expand, as necessary," the registrant's IRM educational and compliance assurance activities based on information the registrant learns from the annual survey and other sources. Because the Compliance Assurance Program describes the industry approach to IRM compliance and provides a number of options and avenues for the registrants to choose from, this document

[7] The provisions of this paragraph are intended to address individuals and entities that perform the functions of a seed dealer for registrants or their licensees, regardless of the specific titles used for such individuals and entities.

cannot provide all the details and features of the registrants' IRM compliance assurance activities. However, additional details of the registrants' IRM educational and compliance assurance activities will be provided annually to EPA on or before January 31 of each year as required under the terms of the Bt Corn registrations.

Attachment 1

Summary of Responses Under the Phased Compliance Approach

This table summarizes the various responses that a registrant may undertake to address growers who are not in full compliance with the IRM requirements.

	Mandatory Responses	**Additional Responses**[8]
Significant Deviations	• IRM Education • Warning Letter • Compliance Assistance Contact (Prior to Planting) • Compliance Assessment Contact (in the Following Growing Season) • Deny Access to the Bt Corn Product for Any Significant Deviation Two Years in a Row	• Invoice Monitoring • Technical Assistance • Grower IRM Training • Reaffirmation of IRM Obligations • Deny Access to the Bt Corn Product for Other Deviations that Are Repeated Over a Period of Years
Other Deviations	• IRM Education • Letter and/or Compliance Assistance Contact (Prior to Planting) • Compliance Assessment Contact (in the Following Growing Season)	

[8] Each individual registrant may, as appropriate, select any (or none) of these supplemental responses, in addition to the mandatory responses indicated, in order to address specific instances of grower noncompliance.

Jeannine Kausch/DC/USEPA/US
10/07/2008 06:43 AM

To "GAO, YONG [AG/1000]" <yong.gao@monsanto.com>
cc
bcc
Subject RE: Compliance Assurance Programs (CAP) Submission for MON 89034 and MON 89034 x MON 88017

Yong,

Thanks for the update and for getting the requested documents out so quickly.

Regards,

Jeannine

"GAO, YONG [AG/1000]" <yong.gao@monsanto.com>

"GAO, YONG [AG/1000]" <yong.gao@monsanto.com>
10/06/2008 03:11 PM

To Jeannine Kausch/DC/USEPA/US@EPA
cc
Subject RE: Compliance Assurance Programs (CAP) Submission for MON 89034 and MON 89034 x MON 88017

Dear Jeannine,

The two documents are on the way to Monsanto's DC office by FedEx. Our staff will deliver them to EPA office once receipted.

Regards,

Yong

Yong Gao, Ph.D.|Regulatory Affairs Manager
U.S. Regulatory Affairs Team|Monsanto Company
St Louis, Missouri 63167, USA|yong.gao@monsanto.com
314 694-2943 (o)|314 488-0971 (m)|314 694-3080 (fax)

-----Original Message-----
From: GAO, YONG [AG/1000]
Sent: Friday, October 03, 2008 3:00 PM
To: 'Kausch.Jeannine@epamail.epa.gov'
Subject: RE: Compliance Assurance Programs (CAP) Submission for MON 89034 and MON 89034 x MON 88017

Dear Jeannine,

We will send the documents to you early next week. Thanks and have a nice weekend.

Yong

Yong Gao, Ph.D.|Regulatory Affairs Manager
U.S. Regulatory Affairs Team|Monsanto Company
St Louis, Missouri 63167, USA|yong.gao@monsanto.com
314 694-2943 (o)|314 488-0971 (m)|314 694-3080 (fax)

-----Original Message-----
From: Kausch.Jeannine@epamail.epa.gov [mailto:Kausch.Jeannine@epamail.epa.gov]
Sent: Friday, October 03, 2008 1:22 PM
To: GAO, YONG [AG/1000]
Subject: Compliance Assurance Programs (CAP) Submission for MON 89034 and MON 89034 x MON 88017

Hi Dr. Gao,

I am in receipt of one of the conditions of registration for MON 89034 and MON 89034 x MON 88017. One of the members of the Insect Resistance Management (IRM) Team has quickly taken a look at the cover letter dated September 22, 2008 and has requested that the following items be submitted to the Agency as soon as possible:

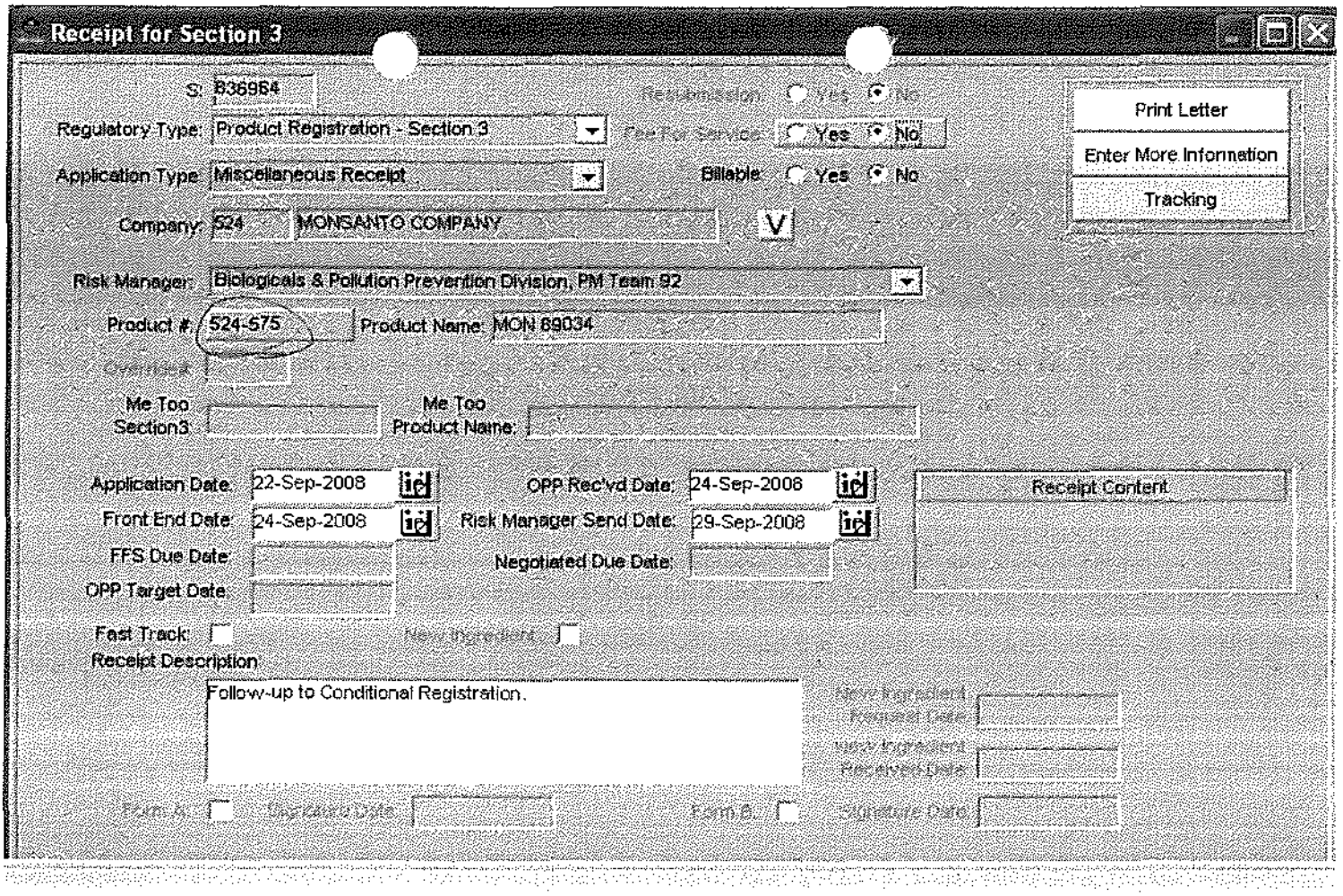
"Bt Corn IRM Compliance Assurance Program" developed by the Agricultural Biotechnology Stewardship Technical Committee (dated September 23, 2002)
"Revised IRM Compliance Assurance Program for Corn Event MON 863" developed by Monsanto and approved by the Agency on August 11, 2006

Please let me know if you have any questions regarding the request of the IRM reviewer.

Thanks for your cooperation,

Jeannine Kausch

Environmental Protection Specialist
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
(703) 347-8920 (telephone)
(703) 305-0118 (fax)



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SEP 2 9 2008

IRM for Monsanto: for Alan's IRM Team.

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MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
http://www.monsanto.com

September 22, 2008

Dr. Sheryl Reilly, Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
United States Environmental Protection Agency
Washington, DC 20460

Subject: Conditions of Registration for MON 89034 (EPA Reg No. 524-575) and MON 89034 x MON 88017 (EPA Reg No. 524-576)

Dear Dr. Reilly:

On June 10, 2008, Monsanto received conditional registration approvals for MON 89034, EPA Reg. No. 524-575, and MON 89034 x MON 88017, EPA Reg. No. 524-576. The registrations require Monsanto to prepare and submit a written description of compliance assurance programs (CAP) for MON 89034 (YieldGard VT PRO) and MON 89034 x MON 88017 (YieldGard VT Triple PRO).

Accordingly, Monsanto plans to meet CAP requirements in the following manner:

1. For the lepidopteran trait conferred by MON 89034, Monsanto will follow the existing "Bt Corn IRM Compliance Assurance Program" developed by the Agricultural Biotechnology Stewardship Technical Committee (ABSTC) (dated September 23, 2002) with one modification. In "Section 2.5.1. Evaluating the Significance of Non-compliance" (page 8), what constitutes a significant deviation is modified as following:

   Either of the following types of non-compliance is deemed to constitute a *significant deviation*:

   - **A Bt grower has planted less than a 15 percent (15%) non-Bt Corn refuge; or**
   - **Fewer than two-thirds (2/3) of the Bt Corn fields are planted within one-half (½) mile of a non-Bt Corn refuge.**

   This modification is consistent with MON 89034 structured refuge requirements for the two registrations.

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2. For corn rootworm trait conferred by MON 88017, Monsanto will follow the existing "Revised IRM Compliance Assurance Program for Corn Event MON 863" developed by Monsanto and approved by EPA dated August 11, 2006 with one modification. In "Section E1 Evaluating the Significance of Non-compliance Instances" (page 7), what constitutes a significant deviation is modified as following:

   Either of the following types of noncompliance is deemed to constitute a *significant deviation*:

   - **a MON 88017 corn grower has planted less than 15% non-Cry3Bb1 *Bt* corn as a refuge; or**
   - **fewer than two-thirds (2/3) of the MON 88017 corn fields are planted within or adjacent to a non-Cry3Bb1 *Bt* corn refuge; or**
   - **fewer than two-thirds (2/3) of the in-field strips are at least four rows wide.**

   This modification is consistent with the current ABSTC practice and the MON 89034 x MON 88017 registration.

Monsanto has modified the existing Technology/Stewardship Agreement (i.e., grower agreement) to include MON 89034 (trade name: YieldGard VT PRO) and MON 89034 x MON 88017 (trade name: YieldGard VT Triple PRO), in which growers are required to comply with IRM requirements (a copy of this grower agreement was submitted to EPA on July 29, 2008).

Broad IRM requirements of each product are specified in the Monsanto Technology Use Guide (TUG) which is referenced in the grower agreement. A copy of the 2009 Monsanto TUG is attached herein (it should be noted that only YieldGard VT Triple PRO will be marketed in the US in 2009). In addition, a more detailed 2009 IRM Guide for the YieldGard family of products will be available to growers in early 2009.

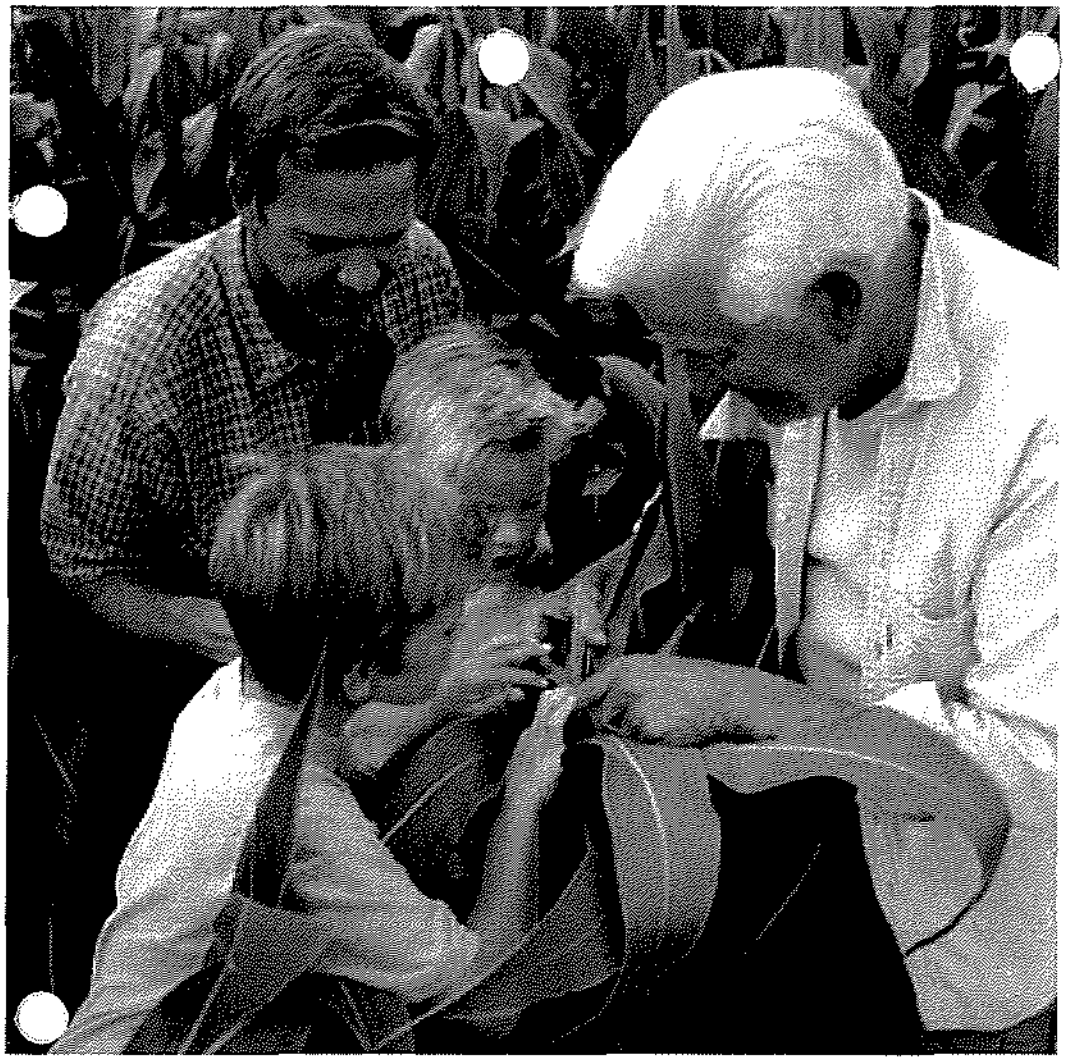
If you have any questions regarding this correspondence please feel free to contact Dr. Russell Schneider, Senior Director, Monsanto Regulatory Affairs and Policy at (202) 383-2866, or me at (314) 694-2943 or yong.gao@monsanto.com.

Sincerely,

Yong Gao, Ph.D.
Regulatory Affairs Manager

Attachment: 2009 Monsanto Technology Use Guide

cc: Russell Schneider, Monsanto
Carolyn Carrera, Monsanto



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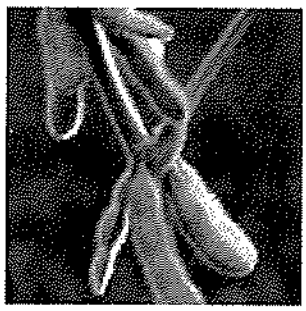

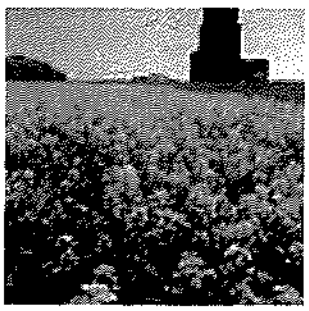

TECHNOLOGY USE GUIDE 2009

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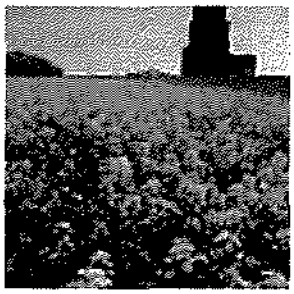
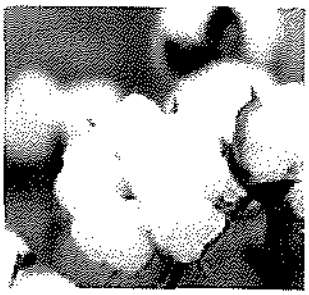
TUG SUPPLEMENTS



TECHNOLOGY USE GUIDE 2009

*INSTRUCTIONS: The information provided in this Supplement supersedes and expands sections in the 2009 Technology Use Guide (TUG). Insert this Supplement packet in your 2009 TUG to ensure you have the most current information.

As a condition of your Monsanto License Agreement, this Supplemental TUG content, along with the other information provided in the TUG, must be read and followed.

The EPA Has Approved YieldGard VT Triple PRO™ with a 20% Refuge in All Growing Areas

YieldGard VT Triple PRO

YIELDGARD VT TRIPLE PRO IS NOW APPROVED FOR 2009 PLANTING IN THE U.S.

YieldGard VT Triple PRO™ is a new corn technology and is now being made available in selected areas.* It features:

- Broader spectrum lepidopteran insect control: Corn earworm, European corn borer, Fall armyworm, Southwestern corn borer, Southern cornstalk borer, Corn stalk borer and Sugarcane borer.
- Reduced insect damage from corn ear-feeding pests which can reduce mycotoxin contamination and increase yields.
- Dual mode-of-action, which allows for lower corn borer refuge acres in southern cotton-growing areas* compared to other registered *B.t.* traited products—a low 20% refuge requirement.

It's the strongest pest management solution on the market, and offers reduced corn borer refuge requirements in the cotton-growing areas—from 50% down to 20%.

In the non-cotton growing areas, YieldGard TV Triple PRO has the same 20% refuge requirement as that for YieldGard VT Triple® and YieldGard® Plus.

**Refer to the current Technology Use Guide for a map depicting the cotton-growing areas.*

YIELDGARD VT TRIPLE PRO CORN REFUGE REQUIREMENTS

- The refuge area must represent at least 20% of the grower's total corn acres (YieldGard VT Triple PRO plus refuge acres).
- A common refuge serves as the refuge for **both corn borer and corn rootworm.** The common refuge offers flexibility by combining the corn borer and corn rootworm refuges into one effective corn refuge.
- It can be **within** or **adjacent** to the YieldGard VT Triple PRO field. If adjacent, it can be separated by a road, path, ditch, etc., but not by another field.
- This refuge must be planted with corn hybrids that do **not** contain *B.t.* technologies. The refuge can be planted with Roundup Ready® Corn 2 or conventional corn.
- Refuge can be planted as a block, strips within the field, or as a perimeter around the field. If perimeter or strips are used for the refuge, the strips must be at least four consecutive rows wide.
- The common refuge can be treated with a soil-applied, seed-applied, or foliar-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*B.t.* foliar insecticide for control of late-season pests (i.e. corn borer), if pest pressure reaches an economic threshold for damage. However, if rootworm adults are present at the time of foliar application, then the YieldGard VT Triple PRO field must be treated in a similar manner.
- A separate refuge option is also available to growers in the Corn Belt. (For more details, see the YieldGard VT Triple and YieldGard Plus separate refuge configuration options in the current Technology Use Guide.) The separate refuge option is not available in cotton-growing areas due to lack of availability of appropriate refuge products.
- If planting with other *B.t.* crops, each *B.t.* crop must have its own specific refuge as described in the Technology Use Guide.

Endangered Species Initiative Supplement to Monsanto Technology/ Stewardship Agreement And Technology Use Guide (TUG)

INTRODUCTION

As part of our commitment to sustainable agriculture and rigorous environmental stewardship, Monsanto is implementing the Glyphosate Endangered Species Initiative to protect threatened and endangered plant species (TES) from any potential adverse effects of the application of glyphosate to crops containing Roundup Ready® technology. This is an important step in preserving our natural heritage and protecting growers' options to use glyphosate-based herbicides on all agricultural lands.

Relatively few growers will be affected by this initiative:

- Use Limitation Areas cover no more than 1% of U.S. cropland.
- Some states have no TES habitats near land used for crop production.
- Ground applications with a use rate of less than 3.5 lbs of glyphosate a.e./acre are *not* affected *(most uses).*

Beginning Sept. t, 2008, provisions of the updated Technology Use Guide will be effective, and growers licensed to purchase and use seeds containing Roundup Ready technology (except growers making only ground applications with a use rate of less than 3.5 lbs of glyphosate a.e./acre) will need to log on to the website www.pre-serve.org before making agricultural applications of glyphosate-based herbicide products with Monsanto licensed technologies. This website will guide growers and applicators through a simple four-step process to determine whether their fields planted to crops containing Roundup Ready technology fall within Use Limitation Areas—areas where threatened or endangered plant species may be present—and, if so, what steps must be taken to reduce risks to threatened and endangered plants.

The mitigation measures described on the website are appropriate for all applications of glyphosate-based herbicides to all crop lands.

SUPPLEMENT TO MONSANTO TECHNOLOGY/STEWARDSHIP AGREEMENT:

The following provision is added to the 2009 Monsanto Technology/Stewardship Agreement:

Licensee agrees to comply with Monsanto's Glyphosate Endangered Species Initiative to protect threatened and endangered plant species from any potential adverse effects of the application of glyphosate to crops containing Roundup Ready technology, as that initiative is specified in the Supplement to the Technology Use Guide.

SUPPLEMENT TO THE 2009 TECHNOLOGY USE GUIDE ENDANGERED SPECIES INITIATIVE:

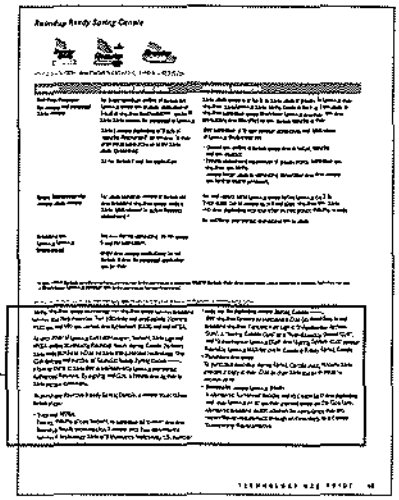
Before making applications of glyphosate-based herbicide products, licensed growers of crops containing Roundup Ready technology must access the website www.pre-serve.org to determine whether any mitigation requirements apply to the planned application to those crops, and must follow all applicable requirements. The mitigation measures described on the website are appropriate for all applications of glyphosate-based herbicides to all crop lands.

Growers making only ground applications to crop land with a use rate of less than 3.5 lbs of glyphosate a.e./acre are *not* required to access the website.

If a grower does not have web access, the seed dealer can access the website on behalf of the grower to determine the applicable requirements, or the grower can call 1-800-332-3111 for assistance.

Farmers Are No Longer Required to Purchase a Canola Use Agreement (CUA)

THE CUA INFORMATION FROM PAGE 45 HAS CHANGED



REPLACE WITH THE FOLLOWING COPY:

As with other Monsanto trait technologies, growers must sign an MTSA before purchasing Roundup Ready® Spring Canola. Growers who observe, respect, and support the MTSA are protecting their own interest by utilizing the technology in the proper way and by helping maintain a "level playing field" for all users of the technology. This enables research and development to continue so that new technologies which further boost efficiency and productivity can be brought to market.

Farmers are no longer required to purchase a Canola Use Agreement (CUA)

AMEND THE ASTERISKED FOOTNOTE ON PAGE 45 TO THE "WEED CONTROL RECOMMENDATIONS (SPRING-SEEDED)" TO THE FOLLOWING:

*If using another Roundup agricultural herbicide, you must refer to the label booklet or separately published Roundup Ready Canola supplemental label for that brand to determine appropriate use rates. If using Roundup PowerMAX®, application rates are the same as for Roundup WeatherMAX®.

RESPECT THE REFUGE®

Insect Resistance Management

Planting Refuges, Preserving Technology

Before opening a bag of seed, be sure to read and understand the stewardship requirements, **including applicable refuge requirements for insect resistance management,** for the biotechnology traits expressed in the seed as set forth in the Monsanto Technology Agreement that you sign. By opening and using a bag of seed, you are reaffirming your obligation to comply with those stewardship requirements.

Market Choices

Grain harvested from products that bear this mark is fully approved for food and feed use in the United States and Japan, but is not approved in the European Union. You must find a market for this crop that will not ship this grain or its processed products to Europe. Appropriate markets for this grain include: domestic feed use or grain handlers that specifically agree to accept this grain and handle it appropriately. For more information on your grain market options, go to the American Seed Trade Association's website at *www.amseed.org* or call your seed supplier.

MARKET CHOICES® is a registered certification mark used under license from ASTA.

Know Before You Grow™, an information service provided by National Corn Growers Association at *www.ncga.com*.

IMPORTANT: Grain Marketing and Seed Availability: YieldGard VT Triple PRO has received the necessary approvals in the United States, however, as of August 28 2008, approvals have not been received in major corn export markets. YieldGard VT Triple PRO will not be launched and seed will not be available until after import approvals are received in appropriate major corn export markets. When launched, YieldGard VT Triple PRO will bear the Market Choices® mark, indicating the need to find a market for the crop that will not ship the grain or its processed products to the E.U. It is a violation of national and international law to move material containing biotech traits across boundaries into nations where import is not permitted. Other stewardship requirements may apply; consult with your seed representative for current stewardship information.

IMPORTANT: The following information is current as of August 28 2008: YieldGard Plus and YieldGard Rootworm with Roundup Ready Corn 2 are grandfathered for import and use in processed feed in the E.U. YieldGard Plus with Roundup Ready Corn 2, YieldGard VT Rootworm/RR2 and YieldGard VT Triple are neither approved nor grandfathered and there is zero tolerance for these traits in processed feed imported in the E.U. Growers of all products bearing the Market Choices mark must talk to their grain handler to confirm the handler's buying position for grain from these products. It is a violation of national and international law to move material containing biotech traits across boundaries into nations where import is not permitted.

B.t. traited products may not be registered in all states. Check with your seed representative for the registration status in your state.

ALWAYS READ AND FOLLOW PESTICIDE LABEL DIRECTIONS. Roundup Ready® crops contain genes that confer tolerance to glyphosate, the active ingredient in Roundup® agricultural herbicides. Roundup® agricultural herbicides will kill crops that are not tolerant to glyphosate. Bollgard®, Bollgard II®, Roundup®, Roundup PowerMAX®, Roundup Ready®, Roundup Technology®, Roundup WeatherMAX®, Transorb & Design®, YieldGard®, YieldGard VT and Design®, YieldGard VT Triple®, YieldGard VT Triple PRO™, and Monsanto imagine® and the vine symbol are trademarks of Monsanto Technology LLC. Respect the Refuge and Corn Design® is a registered trademark of National Corn Growers Association. ©2008 Monsanto Company. [18228jpgd] 5A-9Y-08-3433

Introduction

This 2009 Technology Use Guide (TUG) provides a concise source of technical information about Monsanto's current portfolio of technology products, and sets forth the requirements and guidelines for the use of these products. As a user of Monsanto Technology, it is important that you are familiar with and follow certain management practices. Please read all of the information pertaining to the technology you will be using, including stewardship and related information.

This technical bulletin is not a pesticide product label. It is intended to provide additional information and to highlight approved uses from the product labeling. Read and follow all precautions and use instructions in the label booklet and separately published supplemental labeling for the Roundup® agricultural herbicide product you are using.

Included in this guide is information on the following:

If you have any questions, contact your Authorized Retailer or Monsanto at 1-800-ROUNDUP.

TECHNOLOGY/STEWARDSHIP AGREEMENT

Farmers who purchase Monsanto's traited seed for planting are required to execute the Monsanto Technology Stewardship Agreement (MTSA) and are required to refer to and comply with Monsanto's current TUG.

STEWARDSHIP OVERVIEW

A Message About Stewardship

SEED AND TRAITS

Monsanto Company is committed to enhancing farmer productivity and profitability through the introduction of new modern agricultural biotechnology seed trait technologies (traits). These new technologies bring enhanced value and benefits to farmers, and farmers assume new responsibilities for proper management of those traits. Farmers planting seed with biotech traits agree to implement good stewardship practices, including, but not limited to:

- Reading, signing and complying with the MTSA and reading all annual license terms updates before purchase or use of any seed containing a trait.
- Reading and following the directions for use on all product labels and following applicable stewardship practices as outlined in this TUG and the appropriate Insect Resistance Management (IRM) guide(s).
- Observing regional planting restrictions such as those for Bollgard® or Bollgard II® in certain Texas counties, South Florida, Hawaii, Puerto Rico and the U.S. Virgin Islands.
- Complying with any additional stewardship requirements, such as grain or feed use agreements or geographical planting restrictions, that Monsanto deems appropriate or necessary to implement for proper stewardship or regulatory compliance.
- Following the Weed Resistance Management Guidelines to minimize the risk of resistance development.
- Complying with the applicable IRM practices for specific biotech traits as *mandated* by the Environmental Protection Agency (EPA) and set forth in this TUG.
- Utilizing all seed with biotech traits only for planting a single crop.
- Selling harvested corn with biotech traits not yet fully approved by the European Union (E.U.) only to grain handlers that confirm their acceptance, or using that grain as on-farm feed.
- Not moving material containing biotech traits across boundaries into nations where import is not permitted.
- Not selling, promoting and/or distributing within a state where the product is not yet registered.

If you have questions about seed stewardship or become aware of individuals utilizing biotech traits in a manner other than as noted above, please call 1-800-768-6387. Letters reporting unacceptable or unauthorized use of biotech traits may be sent to:

Monsanto Trait Stewardship
800 N. Lindbergh Boulevard C3ND
St. Louis, MO 63167

Provide Anonymous or Confidential reports as follows:

"Anonymous" reporting results when a person reports information to Monsanto in such a way that the identity of the person reporting the information can not be identified. This kind of reporting includes telephone calls requesting anonymity and unsigned letters.

"Confidential" reporting results when a person reports information to Monsanto in such a way that the reporting person's identity is known to Monsanto. Every effort will be made to protect a person's identity, but it is important to understand that a court may order Monsanto to reveal the identity of people who are "known" to have supplied relevant information.

STEWARDSHIP OVERVIEW

Why is Stewardship Important?

Each component of stewardship offers benefits to farmers:

- Signing the MTSA provides farmers access to Monsanto's biotech-trait seed technology.
- Following IRM guidelines guards against insect resistance to *Bacillus thuringiensis* (*B.t.*) technology and therefore enables the long-term viability of this technology, and meets EPA requirements.
- Good grain and processed products stewardship helps to preserve a continuous open export market for U.S. grain products.
- Proper weed management maintains the long-term effectiveness of glyphosate-based weed control solutions.
- Utilizing biotech seed only for planting a single-commercial crop allows investment for future biotech innovations which will even further improve farming technology.

Practicing these stewardship activities will enable biotechnology's positive agricultural contributions to continue.

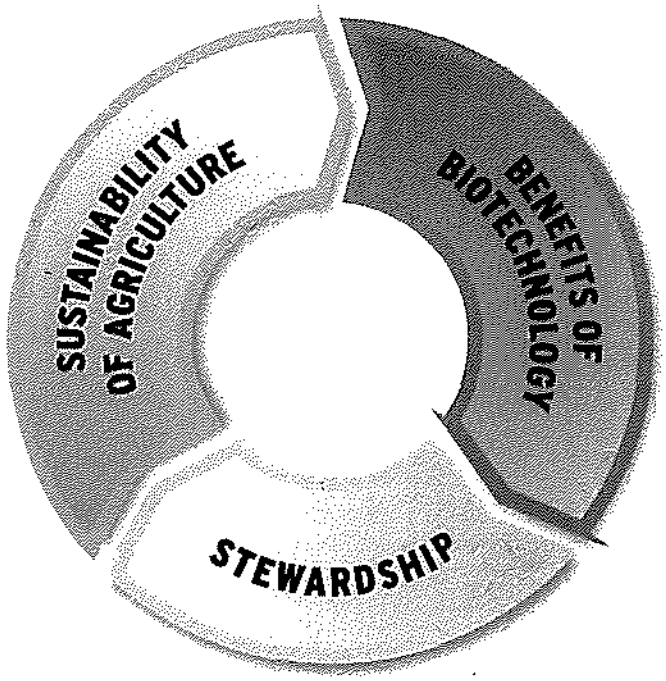
Since 1996, biotech crops have delivered over a decade of environmental and economic benefits to both farmers and consumers.

Biotech crops have:

- Been grown by 8.25 million farmers worldwide.
- Increased farmers' net income by $27 billion.
- Saved 475 million gallons of diesel fuel through reduced tillage or plowing.
- Decreased pesticide applications by 172,000 metric tons.*
- Eliminated greenhouse gas emissions through fuel savings by 10 million metric tons.
- Decreased the environmental impact quotient (EIQ) by 14%.
- Had no (zero) reliably documented human or animal safety issues.
- Been ingredients of an estimated 1 trillion meals consumed.

To learn more, go to: **www.biotech-gmo.com.**

Farmers' attitudes and adoption of sound stewardship principles, coupled with biotechnology benefits, provide for the sustainability of our land resources, biotechnology and farming as a preferred way of life.



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*Pesticides registered by the U.S. EPA will not cause unreasonable adverse effects to man or the environment when used in accordance with label directions.

INSECT RESISTANCE MANAGEMENT

An **EFFECTIVE** IRM program is a vital part of responsible product stewardship for insect-protected biotech products. Monsanto is committed to implementing an effective IRM program for all of its insect-protected *B.t.* technologies in all countries where they are commercialized, including promoting farmer awareness of these IRM programs. Monsanto works to develop and implement IRM programs that strike a balance between available knowledge and practicality, with farmer acceptance and implementation of the plan as critical components.

In the U.S., **the EPA requires** that Monsanto, and farmers who purchase YieldGard®/YieldGard VT® corn products and Bollgard®/Bollgard II® cotton products, implement an IRM plan for these insect-protected products. The IRM programs for YieldGard/YieldGard VT corn products and Bollgard/Bollgard II cotton products are based upon an assessment of the biology of the major target pests, realistic consideration of farmer needs and practices, and an understanding of appropriate pest management practices. These **mandatory regulatory programs** have been developed and updated through broad cooperation with farmer and consultant organizations, including the National Corn Growers Association and the National Cotton Council, extension specialists, academic scientists, and regulatory agencies.

The IRM programs for YieldGard/YieldGard VT corn products and Bollgard/Bollgard II cotton products contain several important elements. One key component of an IRM plan is a refuge. A refuge is simply a block of the relevant crop (corn for YieldGard/YieldGard VT and cotton for Bollgard/Bollgard II, respectively) that does not contain a *B.t.* technology for the control of the insect pests which are controlled by the planted technology(ies). The lack of exposure to the *B.t.* proteins means that there will be susceptible insects nearby to mate with any rare resistant insects that may emerge from *B.t.* products. Susceptibility to the *B.t.* products is then passed on to their offspring, preserving the long-term effectiveness of the technology. Farmers who purchase YieldGard/YieldGard VT corn and Bollgard/Bollgard II cotton products are required to plant an appropriately designed refuge in association with their fields. How large these refuge areas need to be, how they should be placed relative to the YieldGard/YieldGard VT corn and Bollgard/Bollgard II cotton fields, and how they should be managed is described in detail in the sections on those products within this document and the appropriate IRM guide. To download the appropriate IRM guide, go to www.monsanto.com.

Failure to follow IRM guidelines and properly plant a refuge may result in the loss of a farmer's access to Monsanto technologies. Monsanto is committed to the preservation of these technologies. Please do your part to ensure that YieldGard/YieldGard VT corn and Bollgard/Bollgard II cotton technologies are preserved by implementing an IRM plan on your farm.

MONITORING PROGRAM

Monsanto is required to take corrective measures in response to a finding of non-compliance. Monsanto or an approved agent of Monsanto will monitor refuge management practices. The MTSA signed by a farmer requires that upon request by Monsanto or its approved agent, a farmer is to provide the location of all fields planted with YieldGard, YieldGard VT, Bollgard and Bollgard II technologies and the locations of all associated refuge areas, to cooperate fully with any field inspections, and allow Monsanto to inspect all YieldGard, YieldGard VT, Bollgard and Bollgard II fields and refuge areas to ensure an approved insect resistance program has been followed. All inspections will be performed at a reasonable time and arranged in advance with the farmer so that the farmer can be present if desired.

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WEED RESISTANCE MANAGEMENT

Monsanto considers product stewardship to be a fundamental component of customer service and responsible business practices. As leaders in the development and stewardship of Roundup® agricultural herbicides and other products, Monsanto invests significantly in research to continuously improve the proper uses and stewardship of our proprietary herbicide brands. This research, done in conjunction with academic scientists, extension specialists, and crop consultants, includes an evaluation of the factors that can contribute to the development of weed resistance and how to properly manage weeds to delay the development of resistance. Visit **www.weedtool.com** for practical best practices-based advice on reducing the risk for development of glyphosate-resistant weeds. Developed in cooperation with academic experts, the website provides options for managing the risk on a field-by-field basis.

Glyphosate is a Group 9 herbicide based on the mode of action classification system of the Weed Science Society of America. Any weed population may contain plants naturally resistant to Group 9 herbicides. The following general recommendations help manage the risk of weed resistance occurring. More specific recommendations are outlined in each Roundup Ready® crop section in this TUG.

WEED RESISTANCE MANAGEMENT PRACTICES

- Scout your fields before and after herbicide application.
- Start with a clean field, using either a burndown herbicide application or tillage.
- Control weeds early when they are small.
- Add other herbicides (e.g. a selective and/or a residual herbicide) and cultural practices (e.g. tillage or crop rotation) as part of your Roundup Ready cropping system where appropriate.
- Rotation to other Roundup Ready crops will add opportunities for introduction of other modes of action.
- Use the right herbicide product at the right rate and the right time.
- Control weed escapes and prevent weeds from setting seeds.
- Clean equipment before moving from field to field to minimize spread of weed seed.
- Use new commercial seed as free from weed seed as possible.

Monsanto is committed to the proper use and long-term effectiveness of its proprietary herbicide brands through a four-part stewardship program: developing appropriate weed control recommendations, continuing research to refine and update recommendations, education on the importance of good weed management practices, and responding to repeated weed control inquiries through a product performance evaluation program.

Report any incidence of repeated non-performance on a particular weed to the local Monsanto representative, retailer, or county extension agent.

Control of Glyphosate-Resistant Weed Biotypes

Monsanto actively investigates and studies weed control complaints and claims of weed resistance. When glyphosate-resistant weed biotypes have been confirmed, Monsanto alerts farmers, and develops and provides farmers with recommended control measures, which may include additional herbicides or tank-mixes or cultural practices. Monsanto actively communicates all of this information to farmers through multiple channels, including the herbicide label, **www.weedscience.org**, supplemental labeling, this TUG, media and written communications, our website, **www.weedresistancemanagement.com**, and farmer meetings.

Farmers must be aware of and proactively manage for glyphosate-resistant weeds in planning their weed control program. When a weed is known to be resistant to glyphosate, then a resistant population of that weed is by definition no longer controlled with labeled rates of glyphosate. Roundup agricultural herbicide warranties will not cover the failure to control glyphosate-resistant weed populations.

CORN GRAIN STEWARDSHIP

Regulatory Update

The U.S. federal regulatory agencies have granted full clearance to YieldGard® Corn Borer, Roundup Ready Corn 2, and YieldGard Rootworm traits (including all stacks e.g., YieldGard Plus, YieldGard VT Rootworm/RR2®, and YieldGard VT Triple®) for commerce within the U.S., including approval for marketing and consumption as food, and feed for livestock. These products also have food and feed approval in Japan and Canada. However, full regulatory approval for harvested grain/commodities containing certain stacked combinations (YieldGard Rootworm with Roundup Ready Corn 2, YieldGard Plus, YieldGard Plus with Roundup Ready Corn 2, YieldGard VT Rootworm/RR2, and YieldGard VT Triple), is pending in the E.U. As a result, the farmer must find an appropriate market for this grain.

The following table summarizes the approval status of corn products in the E.U. Full E.U. approval is defined as the trait having approval to be used in food, feed, and processed feed.

MANAGEMENT OF POLLEN MOVEMENT

Corn is a naturally cross-pollinated crop, and a minimal amount of pollen movement between neighboring fields is a normal occurrence in its production. It is generally recognized in the industry that a certain amount of incidental, trace level pollen movement occurs, and it is not possible to achieve 100% purity of seed or grain in any corn production system. A number of factors can influence the occurrence and extent of pollen movement. These factors are described in this TUG under the heading "Coexistence and Identity Preserved Production" on page 7. We expect you, as stewards of corn technology pending full E.U. approval, to consider these factors and talk with your neighbors about your cropping intentions.

FULLY APPROVED IN THE E.U.*	APPROVED FOR USE IN PROCESSED FEED IN THE E.U.	NOT APPROVED IN THE E.U.**	REQUIRES MARKET CHOICES	REQUIRES GMCP (see page 6)
YieldGard Corn Borer	YieldGard Rootworm with Roundup Ready Corn 2	YieldGard Plus with Roundup Ready Corn 2	YieldGard Plus	YieldGard Plus with Roundup Ready Corn 2
YieldGard Rootworm	YieldGard Plus	YieldGard VT Rootworm/RR2	YieldGard Rootworm with Roundup Ready Corn 2	YieldGard VT Rootworm/RR2
Roundup Ready Corn 2		YieldGard VT Triple	YieldGard Plus with Roundup Ready Corn 2	YieldGard VT Triple
YieldGard Corn Borer with Roundup Ready Corn 2			YieldGard VT Rootworm/RR2	
			YieldGard VT Triple	

*Approved for food, feed, and processed feed. **Applications filed for food and feed approval.

Products that are not fully approved in the E.U. bear the Market Choices Mark and explanatory statement.

Market Choices®

Grain harvested from products that bear this mark is fully approved for food and feed use in the United States and Japan, but is not approved in the European Union. You must find a market for this crop that will not ship this grain or its processed products to Europe. Appropriate markets for this grain include: domestic feed use or grain handlers that specifically agree to accept this grain and handle it appropriately. For more information on your grain market options, go to the American Seed Trade Association's website at www.amseed.org or call your seed supplier.

MARKET CHOICES® is a registered certification mark used under license from ASTA.

Know Before You Grow®, an information service provided by National Corn Growers Association at *www.ncga.com*.

IMPORTANT: The following information is current as of April 21, 2008: YieldGard Plus and YieldGard Rootworm with Roundup Ready Corn 2 are grandfathered for import and use in processed feed in the E.U. YieldGard Plus with Roundup Ready Corn 2, YieldGard VT Rootworm/RR2 and YieldGard VT Triple are neither approved nor grandfathered and there is *zero tolerance* for these traits in processed feed imported in the E.U. Growers of all products bearing the Market Choices mark must talk to their grain handler to confirm the handler's buying position for grain from these products. **It is a violation of national and international law to move material containing biotech traits across boundaries into nations where import is not permitted.**

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CORN GRAIN STEWARDSHIP

YOUR GRAIN MARKET OPTIONS

Until full E.U. approval is obtained, the farmer must direct grain produced from corn with traits pending full approval in the E.U. to acceptable markets (see below). You must talk to your grain handler about their policies for accepting corn with traits not yet fully approved by the E.U., and inform the grain handler when you deliver grain containing such traits so that it can be managed appropriately.

Appropriate markets for corn harvested with traits pending full approval in the E.U. include:

- Domestic feed use
- Grain handlers who agree to accept this grain and handle it appropriately:
  - grain handlers
  - feedmills
  - feedlots
  - most dry grind ethanol plants

The American Seed Trade Association (ASTA) website at **www.amseed.org** provides a list of grain handlers (Grain Handler's Database) and their positions on accepting corn traits not yet fully approved by the E.U. This information can also be obtained by calling 1-866-SELL CORN or logging onto **www.866sellcorn.com.**

The ASTA **Market Choices®** mark is used to indicate corn products not yet fully approved by the E.U. but ARE FULLY APPROVED for food and feed use in the U.S. and Japan.

Monsanto is committed to promoting corn grain stewardship. The **Grain Marketing Communication Plan (GMCP)** is an initiative by Monsanto implemented to facilitate the proper channeling of grain from corn traits awaiting full approval in the E.U. As part of the GMCP, farmers must communicate to their seed dealers where they plan to sell their harvested corn containing certain traits. Dealers forward this information to Monsanto to validate the willingness of designated grain handlers to properly steward harvested corn not yet fully approved by the E.U. Although corn traits are planted and harvested throughout the U.S., the primary regions from which wet millers draw grain to supply their daily grind is the focal point of the Grain Marketing Communication Plan. The primary region is made up of the full states of Iowa, Illinois, Indiana, Kentucky, Minnesota, Ohio, and Wisconsin, and selected counties in Missouri, Nebraska, North Dakota, and South Dakota. Specific details regarding which traits require a GMCP are communicated separately by Monsanto to farmers and dealers. The farmers should talk with their seed dealer for further details or call 1-866-SELL CORN.

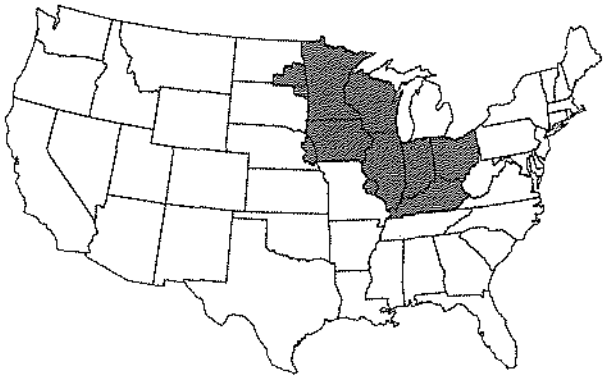
Marketing grain to only grain handlers that acknowledge they will buy grain that includes corn traits that are not yet fully approved by the E.U. is very important.

The most critical corn grain stewardship responsibility for farmers is to talk to their grain handler to verify the handler's acceptance of grain grown from seed containing particular biotechnology traits.

Benefits of good corn grain stewardship:

- Preserves the farmer's choice to use new biotech traits in corn.
- Reinforces the integrity of U.S. agriculture and retains important U.S. export markets for corn products.
- Provides countries importing U.S. grain and/or processed grain the confidence that our channel is reliable.

GMCP Required Geography



NOTE: For certain traits, farmers need to communicate through a GMCP the name(s) of the local grain handler to seed dealers. This is the primary area that grain is sourced to fulfill grind requirements for wet-millers. For more information on those specific locations requiring a GMCP for those traits not yet fully approved by the E.U., please log onto **www.866sellcorn.com** or call 1-866-SELL CORN.

COEXISTENCE AND IDENTITY PRESERVED PRODUCTION

Coexistence in agricultural production systems and supply chains is not new. Different agricultural systems have coexisted successfully for many years around the world. Standards and best practices were established decades ago and have continually evolved to deliver high purity seed and grain to support production, distribution, and trade of products from different agricultural systems. For example, production of similar commodities such as field corn, sweet corn and popcorn has occurred successfully and in close proximity for many years. Another example is the successful coexistence of oilseed rape varieties with low erucic acid content for food use and high erucic acid content for industrial uses.

The introduction of biotech crops generated renewed discussion of coexistence focused on biotech production systems with conventional cropping systems and organic production. These discussions have primarily focused on the potential economic impact of the introduction of biotech products on other systems. The health and safety of biotech products are not an issue because their food, feed, and environmental safety must be demonstrated before they enter the agricultural production system and supply chain.

The coexistence of conventional, organic, and biotech crops has been the subject of several studies and reports. These reports conclude that coexistence among biotech and non-biotech crops is not only possible but is occurring. They recommend that coexistence strategies be developed on a case-by-case basis considering the diversity of products currently in the market and under development, the agronomic and biological differences in the crops themselves, and variations in regional farming practices and infrastructures. Furthermore, coexistence strategies are driven by market needs and should be developed using current science-based industry standards and management practices. The strategies must be flexible, facilitating options and choice for the farmer and the food/feed supply chain, and must be capable of being modified as changes in markets and products warrant.

Successful coexistence of all agricultural systems is achievable and depends on cooperation, flexibility, and mutual respect for each system. Agriculture has a history of innovation and change, and farmers have always adapted to new approaches or challenges by utilizing appropriate strategies, farm management practices, and new technologies.

The responsibility for implementing practices to satisfy specific marketing standards or certification lies with that farmer who is growing a crop to satisfy a particular market. Only that farmer is instructed to employ the practices appropriate to assure the integrity of his/her crop. This is true whether the goal is high-oil corn, white/sweet corn, or organically produced yellow corn for animal feed. In each case, the farmer is seeking to produce a crop that is supported by a market price and consequently that farmer assumes responsibility for satisfying reasonable market specifications. That said, the farmer needs to be aware of the planting intentions of his/her neighbor in order to gauge the need for management practices.

IDENTITY PRESERVED PRODUCTION

Some farmers may choose to preserve the identity of their crops to meet specific markets. Examples of Identity Preserved (I.P.) corn crops include production of seed corn, white, waxy, or sweet corn, specialty oil or protein crops, food grade crops, and any other crop that meets specialty needs, including organic and non-genetically enhanced specifications. Farmers of these crops assume the responsibility and receive the benefit for ensuring that their crop meets mutually agreed contract specifications.

Based on historical experience with a broad range of I.P. crops, the industry has developed generally accepted I.P. agricultural practices. These practices are intended to manage I.P. production to meet quality specifications, and are established for a broad range of I.P. needs. The accepted practice with I.P. crops is that each I.P. farmer has responsibility to implement any necessary processes. These processes may include sourcing seed appropriate for I.P. specifications, field management practices such as adequate isolation distances, buffers between crops, border rows, planned differences in maturity between adjacent fields that might cross-pollinate, and harvest and handling practices designed to prevent mixing and to maintain product quality. These extra steps associated with I.P. crop production are generally accompanied by incremental increases in cost of production and consequently of the goods sold.

COEXISTENCE AND IDENTITY PRESERVED PRODUCTION

General Instructions for Management of Pollen Flow and Mechanical Mixing

For all crop hybrids or varieties that they wish to identity preserve, or otherwise keep separated, farmers should take steps to prevent mechanical mixing. Farmers should make sure all seed storage areas, transportation vehicles, and planter boxes are cleaned thoroughly both prior to and subsequent to the storage, transportation, or planting of the crop. Farmers should also make sure all combines, harvesters and transportation vehicles used at harvest are cleaned thoroughly both prior to and subsequent to their use in connection with the harvest of the grain produced from the crop. Farmers should also make sure all harvested grain is stored in clean storage areas where the identity of the grain can be preserved.

Self-pollinated crops, such as soybeans, do not present a risk of mixing by cross-pollination. If the intent is to use or market the product of a self-pollinated crop separately from general commodity use, farmers should plant fields at a sufficient distance away from other crops to prevent mechanical mixture.

Farmers planting cross-pollinated crops, such as corn or alfalfa, who desire to preserve the identity of these crops or to minimize the potential for these crops to outcross with adjacent fields of the same crop kind, should use the same generally accepted practices to manage mixing that are used in any of the currently grown identity preserved crops of similar crop kind.

Farmers should take into account the following factors that can affect the occurrence and extent of cross-pollination to or from other fields. Information that is more specific to the crop and region may be available from state extension offices.

- **Cross-pollination is limited.** Some plants, such as potatoes, are incapable of cross-pollinating, while others, like alfalfa, require cross-pollination to produce seed. Importantly, cross-pollination only occurs within the same crop kind, like corn to corn.
- **The amount of pollen produced within the field can vary.** The pollen produced by the crop within a given field, known as pollen load, is typically high enough to pollinate all of the plants in the field. Therefore, most of the pollen that may enter from other fields falls on plants that have already been pollinated with pollen that originated from plants within the field. In crops such as alfalfa, the hay cutting management schedule significantly limits or eliminates bloom, and thereby restricts the potential for pollen and/or viable seed formation.
- **The existence and/or degree of overlap in the pollination period of crops in adjacent fields varies.** This will vary depending on the maturity of crops, planting dates, and the weather. For corn, the typical pollen shed period lasts from 5 to 10 days for a particular field. Therefore, viable pollen from neighboring fields must be present when silks are receptive in the recipient field during this brief period to produce any grain with traits introduced by the out-of-field pollen.
- **Distance between fields of different varieties or hybrids of the same crop.** The greater the distance between fields the less likely their pollen will remain viable and have an opportunity to mix and produce an outcross. For wind-pollinated crops, most cross-pollination occurs within the outermost few rows of the field. In fact, many white and waxy corn production contracts ask the farmer to remove the outer 12 rows (30 ft.) of the field in order to remove most of the impurities that could result from cross-pollination with nearby yellow dent corn. Furthermore, research has also shown that as fields become further separated, the incidence of wind-modulated cross-pollination drops rapidly. Essentially, the in-field pollen has an advantage over the pollen coming from other fields for receptive silks because of its volume and proximity to silks.
- **The distance pollen moves.** How far pollen can travel depends on many environmental factors including weather during pollination, especially wind direction and velocity, temperature, and humidity. For bee-pollinated crops, the farmer's choice of pollinator species and apiary management practice may reduce field-to-field pollination potential. All these factors will vary from season to season, and some factors from day to day and from location to location.
- **For wind-pollinated crops, the orientation and width of the adjacent field in relation to the dominant wind direction.** Fields oriented upwind during pollination will show dramatically lower cross pollination for wind-pollinated crops, like corn, compared to fields located downwind.

*YieldGard® and YieldGard VT® Insect-Protected Corn Family**

PRODUCT DESCRIPTION

YieldGard® Corn Borer–YieldGard Corn Borer corn hybrids contain an insecticidal protein from *B.t.* that protects corn plants from specific lepidopteran insect pests. The YieldGard Corn Borer trait delivers whole-plant, full-season protection against European corn borer, southwestern corn borer, sugarcane borer, and southern cornstalk borer resulting in full yield potential. YieldGard Corn Borer corn hybrids also provide intermediate protection** against corn earworm, fall armyworm, and stalk borer. By providing whole-plant protection against corn borer, the genetic yield potential of YieldGard Corn Borer corn hybrids is preserved.

YieldGard Rootworm–YieldGard Rootworm corn hybrids contain an insecticidal protein from *B.t.* that protects corn roots from larval feeding by western, northern, and Mexican corn rootworm. Protecting the root of the corn plant from feeding by corn rootworm larvae decreases lodging and protects the genetic yield potential of YieldGard Rootworm corn hybrids.

All seed containing YieldGard Rootworm technology is treated with seed-applied insecticides.***

YieldGard Plus–YieldGard Plus corn technology combines YieldGard Corn Borer and YieldGard Rootworm technology into a single plant. YieldGard Plus corn hybrids control European and southwestern corn borer, sugarcane borer, southern corn stalk borer, western corn rootworm, northern corn rootworm, and Mexican corn rootworm. YieldGard Plus corn hybrids also provide intermediate protection* against corn earworm, fall armyworm, and stalk borer. By providing in-plant protection against the above insect pests, the genetic yield potential of YieldGard Plus corn hybrids is preserved.

All seed containing YieldGard Plus technology is treated with seed-applied insecticides.***

YieldGard VT Rootworm/RR2®–YieldGard VT Rootworm/RR2 technology is the next generation of YieldGard stacked-trait products that provides better insect control and improved consistency of control of western corn rootworm, northern corn rootworm, and Mexican corn rootworm. Protecting the root of the corn plant from feeding by corn rootworm larvae decreases lodging and protects the genetic yield potential of YieldGard VT Rootworm/RR2 corn hybrids.

The Roundup Ready 2 Technology allows a farmer to experience the benefits of utilizing Roundup agricultural herbicides in a weed control system that provides the broadest weed control spectrum, better application flexibility, and superior crop safety.

All seed containing YieldGard VT Rootworm/RR2 technology is treated with seed-applied insecticides.***

YieldGard VT Triple®–YieldGard VT Triple corn technology combines YieldGard Corn Borer and YieldGard VT Rootworm/RR2 technology into a single plant. YieldGard VT Triple corn hybrids control European and southwestern corn borer, sugarcane borer, southern cornstalk borer, western corn rootworm, northern corn rootworm, and Mexican corn rootworm. YieldGard VT Triple hybrids will also provide intermediate protection against corn earworm, fall armyworm, and stalk borer. By providing in-plant protection against the above insect pests, the genetic yield potential of YieldGard VT Triple corn hybrids is preserved.

YieldGard VT Triple corn hybrids also include Roundup Ready 2 Technology. This trait allows a farmer to experience the benefits of utilizing Roundup agricultural herbicides in a weed control system that provides the broadest weed control spectrum available, along with better application flexibility, and superior crop safety.

All seed containing YieldGard VT Triple technology is treated with seed-applied insecticides.***

YieldGard/YieldGard VT corn products can only be distributed for sale and planted in the states where they are registered. Check with your Monsanto representative for state-specific status or call 1-800-951-9511.

* YieldGard technologies are available in hybrids offered by a variety of seed producers. Farmers must read and follow the limitations and requirements in the appropriate Product Notice or Product Use Guide, including this TUG.

** Protection ranges from partial protection to protection depending on the development stage of the plant when the insects infest the plant.

*** A seed-applied insecticide can protect seed, roots, and seedlings from insects such as black cutworm, wireworm, white grubs, seed corn maggots, chinch bug, and early flea beetles.

YieldGard® and YieldGard VT® Insect-Protected Corn Family

INSECT RESISTANCE MANAGEMENT

Farmers who purchase corn hybrids containing YieldGard® and YieldGard VT® corn traits for planting in 2009 are required by the U.S. EPA to implement an IRM plan. Elements of an IRM program for YieldGard Corn Borer corn, YieldGard Rootworm corn, YieldGard Plus, YieldGard VT Rootworm/RR2®, and YieldGard VT Triple® corn are described in the following sections.

A key component of each IRM plan is the planting of a refuge. A refuge is simply a block or strips of corn that do not contain a *B.t.* technology for the control of the insect pests which are controlled by the planted YieldGard and YieldGard VT corn technology(ies). The lack of exposure to *B.t.* proteins ensures that susceptible insects are nearby to mate with any rare resistant insects that may emerge from YieldGard and YieldGard VT corn hybrids. Susceptibility to the YieldGard and YieldGard VT corn products is then passed on to their offspring, preserving the long-term effectiveness of the technology.

Failure to follow IRM requirements and properly plant a refuge may result in the loss of access to YieldGard and YieldGard VT corn technology. Please do your part to ensure that YieldGard corn technology is preserved by implementing an IRM plan on your farm.

Refer to the Stewardship IRM section on page 3 for additional information regarding the YieldGard IRM Monitoring Program.

Farmers will be notified immediately of any supplemental amendments or changes to the refuge requirements.

Should you observe that other farmers are not implementing IRM requirements for *B.t.* insect-protected corn, please contact Monsanto's Customer Response Center to notify us of such occurrences so that we can investigate: 1-800-768-6387 - Press 2. *You may remain anonymous.*

MULTIPLE-PHASE APPROACH TO INSECT RESISTANCE MANAGEMENT FOR YIELDGARD AND YIELDGARD VT CORN PRODUCTS

Adding a refuge to corn production programs is a requirement for resistance management. In addition to a refuge, other activities are important to IRM:

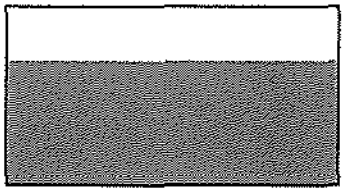
- Plant corn hybrids with YieldGard and YieldGard VT corn technologies to provide consistent protection of corn fields from corn borer and corn rootworm throughout the larval feeding periods.
- Practice Integrated Pest Management (IPM) to preserve the natural enemies of corn borer, corn rootworm, and other insect pests. Natural predators such as lady beetles and ground beetles can help reduce corn borer and corn rootworm larval populations. YieldGard and YieldGard VT insect protection technology aids IPM because it affects only specific insect pests and allows the survival of beneficial insects.
- Farmers should monitor their YieldGard and YieldGard VT technology corn fields and contact their seed dealer or Monsanto at 1-800-951-9511 if they observe any performance problems.

YieldGard Corn Borer Corn Refuge Requirements — Corn-Growing Areas

REFUGES MUST BE ESTABLISHED FOR THE 2009 GROWING SEASON AS FOLLOWS:

- On each farm, plant up to 80 percent of corn acres with YieldGard Corn Borer corn. Plant at least 20 percent of total corn acres to a corn refuge that does not contain a *B.t.* technology that controls European or southwestern corn borer. The refuge corn can be treated with insecticides only when the level of pest pressure meets or exceeds economic thresholds. Sprayable *B.t.* insecticides must not be applied to the refuge corn.
- Plant the refuge corn within, adjacent to, or near YieldGard Corn Borer corn fields. The refuge must be placed within 1/2 mile (1/4 mile or closer preferred) to help provide a population of susceptible insects near the YieldGard Corn Borer corn field. Any field corn hybrid that does not contain a *B.t.* technology which controls European or southwestern corn borer and is planted on a farmer's farm can serve as a refuge.
- Corn refuge options include YieldGard Rootworm, YieldGard Rootworm with Roundup Ready® Corn 2, Roundup Ready Corn 2, YieldGard VT Rootworm/RR2®, and conventional corn but no other *B.t.* product for corn borer management. Popcorn can be used as a refuge option, but sweet corn can not.
- Plant a refuge on every farm where YieldGard Corn Borer corn hybrids are planted.
- Plant the refuge at the same time as YieldGard Corn Borer corn.
- Manage the refuge the same way YieldGard Corn Borer corn is managed. Reducing inputs or planting the refuge on marginal land merely reduces the effectiveness of the refuge.
- Mixing non-*B.t.* seed with YieldGard Corn Borer corn seed for use in the refuge or on any corn acreage is not an acceptable refuge design.
- Farmers can not utilize neighbors' corn fields for their refuge.
- Refuge fields must be owned or managed by the farmer.

Corn Refuge



= YieldGard Corn Borer = Refuge

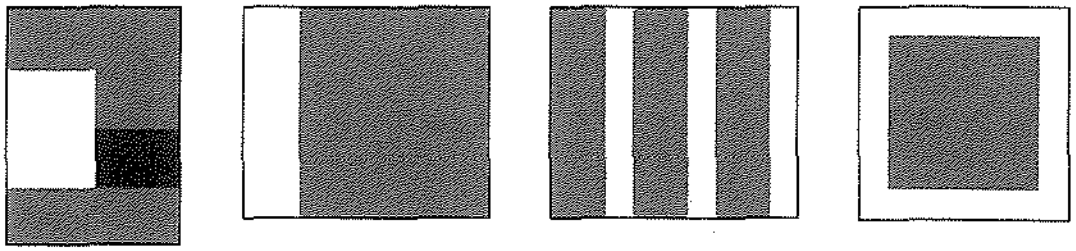
Refuge Configuration Options

The refuge on each farm may be arranged in a number of configurations. These options offer the flexibility to easily incorporate an effective corn refuge into farm operations.

Options include:

- Plant a separate corn refuge within 1/2 mile of each YieldGard Corn Borer corn field (1/4 mile or closer preferred).
- Plant the refuge as a block within a YieldGard Corn Borer corn field.
- Plant field perimeters or end rows to a corn refuge.
- Split the planter to alternate four or more consecutive rows of refuge corn with YieldGard Corn Borer corn.

Separate Field *Block* *Split Planter (Strips)* *Perimeter*



= YieldGard Corn Borer
= Refuge
= Soybeans

Refuge must be within a 1/2 mile of YieldGard Corn Borer (1/4 mile preferred)

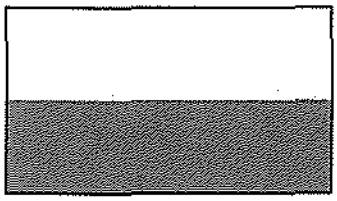
Minimum of 4 rows

YieldGard® Corn Borer Corn Refuge Requirements — Cotton-Growing Areas

In the cotton-growing areas shown below, all the same refuge requirements indicated on page 11 apply, but additional refuge acres are required to meet EPA requirements:

- On each farm a farmer may plant up to 50 percent of their corn acres with YieldGard Corn Borer corn. Plant a minimum of 50 percent of total corn acres with refuge corn. The refuge corn can be treated with insecticides only when the level of pest pressure meets or exceeds economic thresholds. Sprayable *B.t.* insecticides must not be applied to the refuge corn.

Corn Refuge



■ = YieldGard Corn Borer ☐ = Refuge

Southern Region: Cotton-Growing Areas

ALABAMA
All Counties

ARKANSAS
All Counties

FLORIDA**
All Counties

GEORGIA
All Counties

LOUISIANA
All Counties

MISSISSIPPI
All Counties

MISSOURI
Counties of:
Dunklin
New Madrid
Pemiscot
Scott
Stoddard

NORTH CAROLINA
All Counties

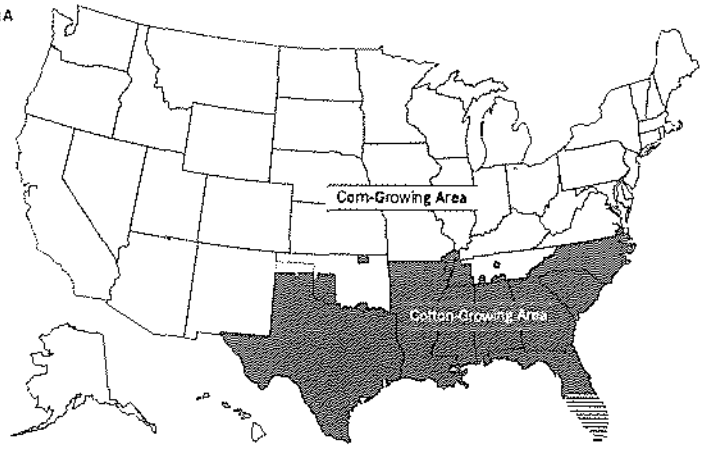
OKLAHOMA
Counties of:
Beckham
Caddo
Comanche
Custer
Greer
Harmon
Jackson
Kay
Kiowa
Tillman
Washita

SOUTH CAROLINA
All Counties

TENNESSEE
Counties of:
Carroll
Chester
Crockett
Dyer
Fayette
Franklin
Gibson
Hardeman
Hardin
Haywood
Lake
Lauderdale
Lincoln
Madison
Obion
Rutherford
Shelby
Tipton

TEXAS*
All Counties EXCEPT
Carson
Dallam
Hansford
Hartley
Hutchinson
Lipscomb
Moore
Ochiltree
Roberts
Sherman

VIRGINIA
Counties of:
Dinwiddie
Franklin City
Greensville
Isle of Wight
Northampton
Southampton
Suffolk City
Surrey
Sussex



*NOTE: Bollgard® or Bollgard II® varieties of cotton are not for commercial planting use in the following counties in the Texas panhandle: Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman.

**NOTE: In Florida, do not plant Bollgard or Bollgard II cotton south of Tampa (Florida Route 60). Commercial culture of Bollgard or Bollgard II cotton is prohibited in Hawaii, Puerto Rico and the U.S. Virgin Islands.

See Page 25 for complete information.

YieldGard Rootworm and YieldGard VT Rootworm/RR2® Corn Refuge Requirements

YIELDGARD ROOTWORM AND YIELDGARD VT ROOTWORM/RR2® CORN IRM REQUIREMENTS ARE THE SAME THROUGHOUT THE UNITED STATES AND CANADA

Refuges must be established for the 2009 growing season as follows:

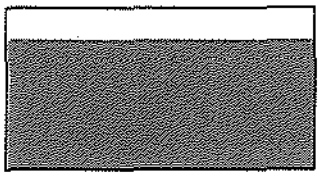
- On each farm, plant up to 80 percent of corn acres with YieldGard Rootworm and YieldGard VT Rootworm/RR2 corn hybrids. Plant at least 20 percent of the corn acres to a corn refuge that does not contain a *B.t.* technology for control of western, northern, or Mexican corn rootworm.
- The corn refuge can be treated for corn rootworm larvae and other soil pests with soil-applied, seed-applied, or foliar-applied insecticides.
- The corn refuge can be treated with a non-*B.t.* insecticide to control late-season pests such as corn borer; however, the YieldGard Rootworm and YieldGard VT Rootworm/RR2 corn must also be treated if sprayed at a time when corn rootworm beetles are present.
- Insecticides labeled for the treatment of corn rootworm adults can be applied to the refuge only if the YieldGard Rootworm or YieldGard VT Rootworm/RR2 field is treated in a similar manner.
- Corn refuge options include YieldGard Corn Borer, YieldGard Corn Borer with Roundup Ready® Corn 2, Roundup Ready Corn 2, and conventional corn, but no *B.t.* product for corn rootworm management.
- Plant the refuge within or adjacent to YieldGard Rootworm and YieldGard VT Rootworm/RR2 corn fields. The corn refuge can be separated by a ditch or a road but not by another field. Alternatively, the refuge may be planted as in-field or perimeter strips. These strips must be at least four consecutive rows wide.
- All refuge fields must be owned by or managed by the farmer.
- Plant a refuge on every farm where YieldGard Rootworm and YieldGard VT Rootworm/RR2 corn hybrids are planted.
- Plant the refuge at the same time as YieldGard Rootworm and YieldGard VT Rootworm/RR2 corn.
- Mixing non-*B.t.* seed with YieldGard Rootworm and YieldGard VT Rootworm/RR2 corn seed for use in the refuge is not permitted.
- If the refuge is planted on first-year corn (rotated corn ground), then the YieldGard Rootworm and YieldGard VT Rootworm/RR2 corn must also be planted on first-year corn (rotated corn ground). If the refuge is planted on continuous corn ground, then the YieldGard Rootworm and YieldGard VT Rootworm/RR2 may be planted on either first-year corn (rotated corn ground) or continuous corn ground.

YieldGard® Rootworm and YieldGard VT Rootworm/RR2® Corn Refuge Configuration Options

The refuge on each farm may be arranged in a number of configurations. These options offer the flexibility to easily incorporate an effective corn refuge into farm operations. Options include:

- Plant a corn refuge within or adjacent to each YieldGard® Rootworm and YieldGard VT Rootworm/RR2® corn field.
- Plant a corn refuge as a block within a YieldGard Rootworm and YieldGard VT Rootworm/RR2 corn field.
- Split the planter to alternate at least four consecutive rows of corn refuge with YieldGard Rootworm and YieldGard VT Rootworm/RR2 corn.
- Plant field perimeters or end rows to a corn refuge.

Corn Refuge

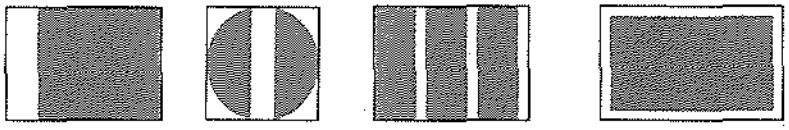


= YieldGard Rootworm or YieldGard VT Rootworm/RR2

= Refuge *(i.e. YieldGard Corn Borer, YieldGard Corn Borer with Roundup Ready® Corn 2, Roundup Ready Corn 2, or conventional corn)*

Examples of Within-Field Configurations

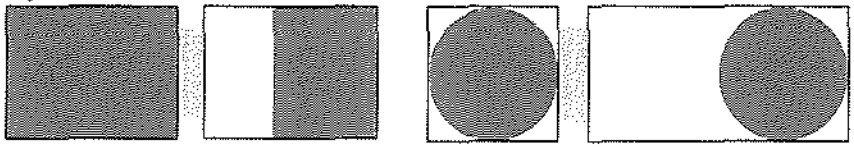
Block *Block* *Split Planter (Strips)* *Perimeter*



Minimum of 4 rows

Examples of Adjacent-Field Configurations

Adjacent *Adjacent*



Separated by road path other field but or by another field

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YieldGard Plus and YieldGard VT Triple® Corn Refuge Requirements for Common and Separate Configuration Options

REFUGE MUST BE ESTABLISHED FOR THE 2009 GROWING SEASON AS FOLLOWS:

Farmers have two choices when planning their refuge strategy for YieldGard Plus and YieldGard VT Triple® corn hybrids. The first option is to plant a refuge that will serve as the refuge for both corn borer and corn rootworm. This option is referred to as the **common refuge** and is described below.

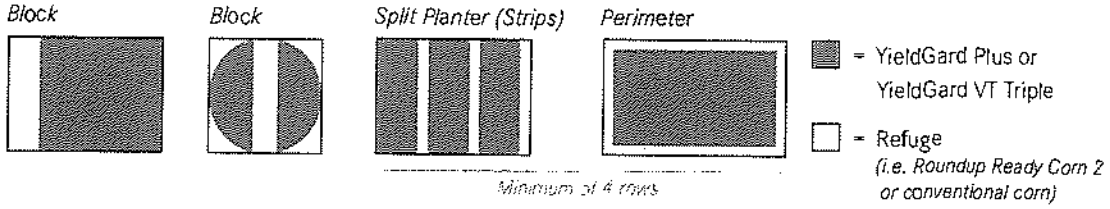
For selected farms and corn-growing regions that typically have high levels of corn borer infestation, there could be significant yield risk associated with planting a common refuge for YieldGard Plus and YieldGard VT Triple. In these situations a second option is available to farmers. This option requires planting a separate refuge for corn borer and corn rootworm. Under this option, the corn borer refuge can be treated with a foliar insecticide for corn borer, and if corn rootworm beetles are present, the YieldGard Plus and YieldGard VT Triple field would not have to be treated in a similar manner. The separate refuge option is described in detail on pages 16-17.

YIELDGARD PLUS AND YIELDGARD VT TRIPLE CORN COMMON REFUGE CONFIGURATIONS

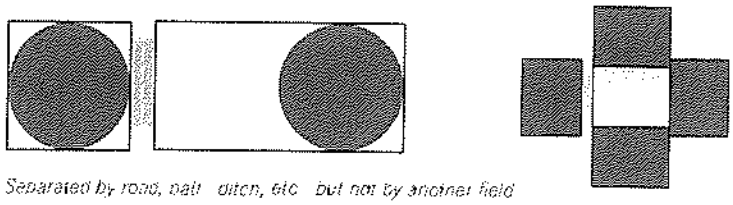
When planting a refuge that will serve as a common refuge for corn borer and corn rootworm, the 2009 growing season requirements are as follows:

- When using a common refuge plan, in **non-cotton-growing regions,** plant up to 80 percent of corn acres with YieldGard Plus and YieldGard VT Triple corn hybrids on each farm. Plant at least 20 percent of the corn acres to a corn refuge that does not contain a *B.t.* technology. In **cotton-growing areas,** plant up to 50 percent of corn acres to YieldGard Plus and YieldGard VT Triple corn hybrids (See page 12 for map and list of cotton-growing areas).
- The common refuge may be treated for corn rootworm larvae and other pests with soil-applied, seed-applied, or foliar-applied insecticides.
- If a late-season pest such as corn borer reaches the economic threshold, the common refuge may be treated with a non-*B.t.* insecticide to control the pest. However the YieldGard Plus and YieldGard VT Triple corn must also be treated if rootworm beetles (adults) are present at the time of the foliar application.
- Corn planted in the common refuge may be Roundup Ready Corn 2 or conventional corn including popcorn, but may not be any *B.t.* corn technology that provides protection from corn borer or corn rootworm. Sweet corn is not allowed.
- The common refuge must be planted within or adjacent to the YieldGard Plus and YieldGard VT Triple corn fields. The refuge may be separated by a ditch or a road, but not by another field. Alternatively, the refuge may be planted as in-field or perimeter strips. These strips must be at least four consecutive rows wide.
- Plant a refuge on every farm where YieldGard Plus and YieldGard VT Triple corn hybrids are planted.
- Plant the refuge at the same time as the YieldGard Plus and YieldGard VT Triple corn.
- Mixing non-*B.t.* seed with YieldGard Plus and YieldGard VT Triple corn seed for use as a refuge is not permitted.
- If the refuge is planted on first-year corn (rotated corn ground), then the YieldGard Plus and YieldGard VT Triple corn must also be planted on first-year corn (rotated corn ground). If the refuge is planted on continuous corn ground, then the YieldGard Plus and YieldGard VT Triple corn may be planted on either first-year corn (rotated corn ground) or continuous corn ground.
- Refuge fields must be owned or managed by the farmer.

Examples of Within-Field Configurations for Common Refuge Option



Examples of Adjacent-Field Configurations for Common Refuge



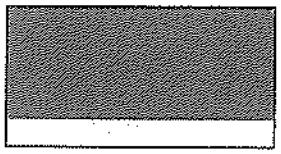
Separated by road, path, ditch, etc. but not by another field

YieldGard® Plus and YieldGard VT Triple® Corn Separate Refuge Configuration Options in Corn (Non-Cotton) Growing Areas Only

This refuge planting option offers farmers the flexibility of controlling corn borer in both corn rootworm and corn borer refuge areas without the need to also spray the YieldGard® Plus and YieldGard VT Triple® corn field.

CORN BORER REFUGE REQUIREMENTS

- The corn borer refuge must represent at least **20 percent of the farmer's** total corn acres (YieldGard Plus or YieldGard VT Triple, YieldGard Corn Borer plus any non-*B.t.* acres). The corn borer refuge must be planted with a hybrid that does not contain a *B.t.* technology for control of European and southwestern corn borer and must be planted within **1/2 mile** (1/4 mile preferred) of the YieldGard Plus or YieldGard VT Triple field.
- Farmers may spray for corn borer control if economic thresholds are reached.
- The corn borer refuge can be Roundup Ready® Corn 2 or conventional corn. Popcorn can be used as a refuge option but sweet corn can not.



*Corn refuge minimum 20% non-*B.t. *refuge*

CORN ROOTWORM REFUGE REQUIREMENTS

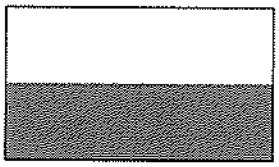
- The corn rootworm refuge must be planted with a hybrid that does not contain a *B.t.* technology for control of western, northern, and Mexican corn rootworm, but can be planted with *B.t.* hybrids that control corn borer (e.g., YieldGard Corn Borer). The corn rootworm refuge must represent at least **20 percent of the farmer's** corn acres (YieldGard Plus or YieldGard VT Triple and YieldGard Corn Borer) and must be planted within or adjacent to the YieldGard Plus or YieldGard VT Triple field as a block, strips within the field, or as a perimeter around the field. If perimeter or in-field strips are used for the refuge, the strips must be at least four consecutive rows wide.

YieldGard Plus and YieldGard VT Triple Corn Separate Refuge Configuration Options in Cotton – Growing Areas Only

This refuge planting option offers farmers the flexibility of controlling corn borer in both corn rootworm and corn borer refuge areas without the need to also spray the YieldGard Plus and YieldGard VT Triple corn field.

CORN BORER REFUGE REQUIREMENTS

- The corn borer refuge must represent at **least 50 percent of the farmer's** total **acres** (YieldGard Plus or YieldGard VT Triple, YieldGard Corn Borer plus any non-*B.t.* acres). The corn borer refuge must be planted with a hybrid that does not contain a *B.t.* technology for control of European and southwestern corn borer and must be planted within **1/2 mile** (1/4 mile preferred) of the YieldGard Plus or YieldGard VT Triple field.
- Farmers may spray for corn borer control if economic thresholds are reached.
- The corn borer refuge can be Roundup Ready Corn 2 or conventional corn. Popcorn can be used as a refuge option, but sweet corn can not.



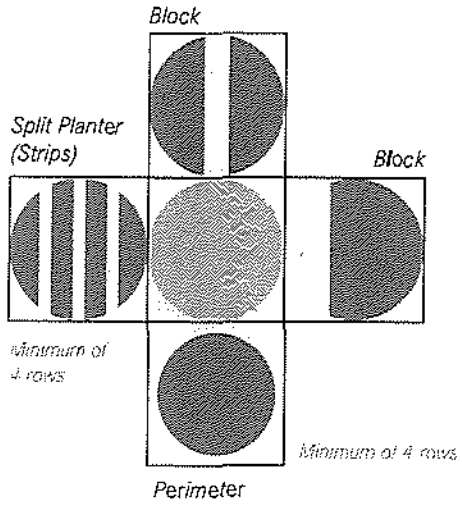
*Corn refuge minimum 50% non-*B.t. *refuge*

CORN ROOTWORM REFUGE REQUIREMENTS

- The corn rootworm refuge must be planted with a hybrid that does not contain a *B.t.* technology for control of western, northern, and Mexican corn rootworm but can be planted with *B.t.* hybrids that control corn borer (i.e. YieldGard Corn Borer). The corn rootworm refuge must represent at least **20 percent of the farmer's** corn acres (YieldGard Plus or YieldGard VT Triple and YieldGard Corn Borer) and must be planted within or adjacent to the YieldGard Plus or YieldGard VT Triple field and can be planted as a block, strips within the field, or as a perimeter around the field. If perimeter or in-field strips are used for the refuge, the strips must be at least four consecutive rows wide.
- For additional refuge requirements for cotton-growing areas, please see page t2.

YieldGard Plus and YieldGard VT Triple Corn Separate Refuge Configuration Options

Examples of Separate Refuge Configurations



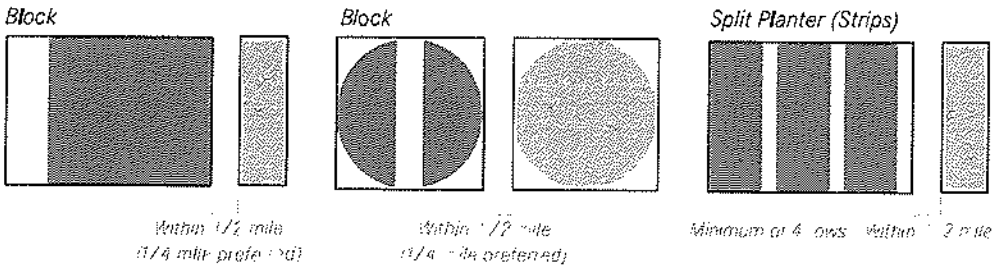
= YieldGard Plus or YieldGard VT Triple

= Corn Rootworm Refuge
(i.e. YieldGard Corn Borer, YieldGard Corn Borer with Roundup Ready Corn 2)

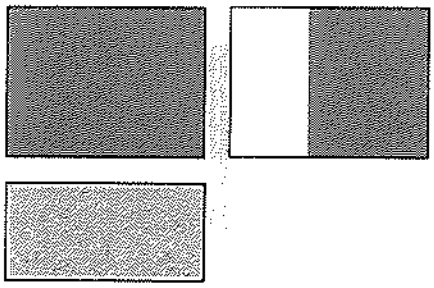
= Corn Borer Refuge*
(i.e. Roundup Ready Corn 2 or conventional corn)

**Corn refuge within 1/2 mile (1/4 mile preferred) of YieldGard Plus and minimum of 20% non-B.t. corn borer corn*

Additional Examples of Separate Refuge Configurations



Adjacent



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YieldGard® with Roundup Ready® Corn 2

YieldGard® Corn Borer with Roundup Ready® Corn 2

PRODUCT DESCRIPTION

YieldGard® Corn Borer with Roundup Ready® Corn 2 offers farmers all the benefits of both traits combined in one crop. These hybrids exhibit the same insect protection qualities as YieldGard Corn Borer and, like Roundup Ready Corn 2, are tolerant to over-the-top applications of Roundup® agricultural herbicides. For more information on Roundup Ready Corn 2, please see pages 19-21 of this guide. For information on Roundup Ready 2 Technology, see page 19.

RECOMMENDED MANAGEMENT PRACTICES

Managing YieldGard Corn Borer with Roundup Ready Corn 2 requires a farmer to follow the recommended management practices associated with corn containing each individual trait.

Farmers of YieldGard Corn Borer with Roundup Ready Corn 2 hybrids must follow the same guidelines for establishing a refuge as described for YieldGard Corn Borer on pages 11-12 of this guide.

YieldGard Rootworm with Roundup Ready Corn 2

PRODUCT DESCRIPTION

YieldGard Rootworm with Roundup Ready Corn 2 offers farmers all the benefits of both traits combined in one crop. These hybrids exhibit the same insect protection qualities as YieldGard Rootworm and, like Roundup Ready Corn 2, are tolerant to over-the-top applications of Roundup agricultural herbicides. For more information on Roundup Ready Corn 2, please see pages 19-21 of this guide.

RECOMMENDED MANAGEMENT PRACTICES

Managing YieldGard Rootworm with Roundup Ready Corn 2 requires a farmer to follow the recommended management practices associated with corn containing each individual trait.

Farmers of YieldGard Rootworm with Roundup Ready Corn 2 hybrids must follow the same guidelines for establishing a refuge and marketing grain as described for YieldGard Rootworm on pages 13-14 of this guide.

YieldGard Plus with Roundup Ready Corn 2

PRODUCT DESCRIPTION

YieldGard Plus with Roundup Ready Corn 2 offers farmers all the benefits of all three traits combined in one crop. These hybrids exhibit the same insect protection qualities of YieldGard Corn Borer and YieldGard Rootworm and, like Roundup Ready Corn 2, are tolerant to over-the-top applications of Roundup agricultural herbicides. For more information on Roundup Ready Corn 2, please see pages 19-21 of this guide.

RECOMMENDED MANAGEMENT PRACTICES

Managing YieldGard Plus with Roundup Ready Corn 2 requires a farmer to follow the recommended management practices associated with corn containing each individual trait.

Farmers of YieldGard Plus with Roundup Ready Corn 2 hybrids must follow the same guidelines for establishing a refuge as described for YieldGard Plus on pages 15-17 of this guide.

YieldGard VT with Roundup Ready 2® Technology

YieldGard VT Rootworm/RR2®

PRODUCT DESCRIPTION

YieldGard VT Rootworm/RR2® technology provides the next generation of YieldGard stacked-trait products that provides better insect control and improved consistency of control of western corn rootworm, northern corn rootworm, and Mexican corn rootworm. Protecting the root of the corn plant from feeding by corn rootworm larvae decreases lodging and protects the genetic yield potential of YieldGard VT Rootworm/RR2 corn hybrids.

RECOMMENDED MANAGEMENT PRACTICES

Managing YieldGard VT Rootworm/RR2 requires a farmer to follow the recommended management practices associated with corn containing each individual trait.

Farmers of YieldGard VT Rootworm/RR2 hybrids must follow the same guidelines for establishing a refuge and marketing grain as described for YieldGard Rootworm on pages 13-14 of this guide. The YieldGard VT Rootworm/RR2 hybrids contain Roundup Ready 2 Technology and are equally as tolerant to Roundup agricultural herbicides as you are used to with Roundup Ready Corn 2.

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YieldGard VT Triple®

PRODUCT DESCRIPTION

YieldGard VT Triple® corn technology combines YieldGard Corn Borer and YieldGard VT Rootworm/RR2 technology into a single plant. YieldGard VT Triple corn hybrids control European and southwestern corn borer, sugarcane borer, southern cornstalk borer, western corn rootworm, northern corn rootworm, and Mexican corn rootworm. YieldGard VT Triple hybrids will also provide some protection against corn earworm, fall armyworm, and stalk borer. By providing in-plant protection against the above insect pests, the genetic yield potential of YieldGard VT Triple corn hybrids is preserved.

YieldGard VT Triple corn hybrids also contain Roundup Ready 2 Technology. This trait allows a farmer to experience the benefits of utilizing Roundup agricultural herbicides in a weed control system that provides the broadest weed control spectrum available, along with better application flexibility, and superior crop safety.

RECOMMENDED MANAGEMENT PRACTICES

Managing YieldGard VT Triple requires a farmer to follow the recommended management practices associated with corn containing each individual trait.

Farmers of YieldGard VT Triple hybrids must follow the same guidelines for establishing a refuge and marketing grain as described for YieldGard VT Triple on pages 15-17 of this guide. The YieldGard VT Triple hybrids contain Roundup Ready 2 Technology and are equally as tolerant to Roundup agricultural herbicides as you are used to with Roundup Ready Corn 2.

Roundup Ready Corn 2

PRODUCT DESCRIPTION

Roundup Ready Corn 2 and corn with Roundup Ready 2 Technology are equivalent in their tolerance to Roundup agricultural herbicides. For ease of reading, all references in the following section on Roundup Ready 2 Technologies include Roundup Ready Corn 2 and YieldGard VT Rootworm/RR2 unless specified as different.

Products with Roundup Ready 2 Technology contain in-plant tolerance to Roundup agricultural herbicides. Farmers are provided excellent crop safety and full yield potential, with applications made from planting through 48" of corn height. Drop nozzles must be used between 30" and 48" of corn height.

Monsanto Brands of Selective Over-The-Top Herbicide Products

Herbicide products sold by Monsanto for use over the top of products with Roundup Ready 2 Technology, for the 2009 crop season are as follows:

- Roundup WeatherMAX®
- Roundup PowerMAX®

For complete information about the use of Roundup agricultural herbicides over the top of products with Roundup Ready 2 Technology, refer to the appropriate product's label booklet or supplemental label.

You may use another glyphosate herbicide, but only if it has federally approved label instructions for use over products with Roundup Ready 2 Technology, and the product and the use label for products with Roundup Ready 2 Technology, have been approved by your specific state. Contact the product manufacturers, the local retailers, or the local extension agents for confirmation that the products carry EPA and state approved labeling for this use. MONSANTO DOES NOT MAKE ANY REPRESENTATIONS, WARRANTIES OR RECOMMENDATIONS CONCERNING THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES WHICH ARE LABELED FOR USE OVER CORN WITH ROUNDUP READY 2 TECHNOLOGY. MONSANTO SPECIFICALLY DENIES ALL RESPONSIBILITY AND DISCLAIMS ANY LIABILITY FOR ANY DAMAGE FROM THE USE OF THESE PRODUCTS OVER THE TOP OF CORN WITH ROUNDUP READY 2 TECHNOLOGY. ALL QUESTIONS AND COMPLAINTS CAUSED BY THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES SHOULD BE DIRECTED TO THE SUPPLIER OF THE PRODUCT IN QUESTION.

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Weed Control Recommendations

The Roundup Ready® 2 Technology system's flexibility, broad-spectrum weed control and proven crop safety offer farmers weed control programs that allow them to use the system in the way that provides the greatest benefit. Farmers can select the program that best fits the way they farm. Options include the use of a residual herbicide with a Roundup® agricultural herbicide, tank-mixing other herbicides with Roundup agricultural herbicides where appropriate and a total postemergence program.

AGRONOMIC PRINCIPLES

Corn yield is very sensitive to early-season weed competition. Weed control systems must provide farmers the opportunity to control weeds before they become competitive. The Roundup Ready 2 Technology system provides a mechanism to control weeds at planting and once they emerge. Failure to control weeds with the right rate, at the right time, and with the right product, can lead to increased weed competition, weed escapes, and the potential for decreased yields. Use other herbicide products with Roundup agricultural herbicides if appropriate for the weed spectrum.

WEED RESISTANCE MANAGEMENT FOR PRODUCTS WITH ROUNDUP READY 2 TECHNOLOGY

Follow the guidelines below to minimize the risk of developing glyphosate-resistant weed populations in a Roundup Ready 2 Technology system.

- Start clean with a burndown herbicide or tillage. Early-season weed control is critical to yield.
- Apply preemergence residual herbicides such as Harness® Xtra, Degree Xtra®, or other residual herbicides at the recommended rate.
- Or apply a preemergence residual herbicide at the recommended rate tank-mixed with Roundup WeatherMAX® at a minimum of 22 oz/A in-crop before weeds exceed 4" in height.
- Follow with a postemergence in-crop application of Roundup WeatherMAX at a minimum of 22 oz/A for additional weed flushes before they exceed 4" in height.
- Roundup WeatherMAX may be tank-mixed with other herbicides for postemergence weed control.
- Report repeated non-performance to Monsanto or your local retailer.

PROGRAM	INSTRUCTIONS AND USE RATES*	ADDITIONAL INFORMATION
For use where residual herbicides are typically used for early-season weed control: **Residual Herbicide Plus Roundup WeatherMAX**	Use the proper Roundup Ready RATE** of Bullet®, Degree, Degree Xtra, Harness, Harness Xtra, Harness Xtra, 5.6L, Micro-Tech®, or Lariat® (no post) as defined in the table below and the individual product labels, either pre or postemergence to the crop.** Follow with Roundup WeatherMAX at 16 to 22 oz/A post sequentially after preemergence application or tank-mixed in-crop with the residual. Applications should be made before weeds exceed 4" in height. **Roundup Ready RATEs***** Harness 1.5 Pints Degree 3.0 Pints Harness Xtra 1.2 Quarts Harness Xtra 5.6L 1.5 Quarts Degree Xtra 2.0 Quarts Micro-Tech 2.0 Quarts Lariat 2.0 Quarts Bullet 2.0 Quarts	Use full labeled rate of residual when application is 14 days or more prior to planting or when tough grasses are present, e.g., barnyardgrass, shattercane, seedling johnsongrass, sandbur. Use a minimum of 2.5 pt/A of Harness on woolly cupgrass and wild proso millet. Products containing atrazine will provide improved control of cocklebur, giant ragweed, *Palmer Amaranth* and morningglory. Tank-mix products such as 2,4-D, dicamba or Status® herbicide with Roundup WeatherMAX for control of glyphosate-resistant marestail (horseweed), *Palmer Amaranth* and other difficult-to-control weeds. Use 22 to 32 oz/A of Roundup WeatherMAX* when morningglory or perennial weeds are present or when broadleaf weeds are 4" in height or taller.
For use where total postemergence programs are effective and sustainable: **Roundup WeatherMAX Sequential**	Apply Roundup WeatherMAX at 16 to 22 oz/A before weeds exceed 4" in height and follow with a second application at 16 to 22 oz/A for an additional flush of weeds before they exceed 4" in height.	Use 22 to 32 oz/A of Roundup WeatherMAX when morningglory or perennial weeds are present. Tank-mix products such as 2,4-D, dicamba or Status herbicide with Roundup WeatherMAX for control of glyphosate resistant marestail (horseweed), *Palmer Amaranth* and other difficult-to-control weeds.
Maximum Use Rates For Roundup WeatherMAX	**Products with Roundup Ready 2 Technology** in-crop: • 32 oz/A per single application • Total: 64 oz/A from emergence through 48" height of corn, drop nozzles must be used from 30" to 48" corn.	**Products with Roundup Ready 2 Technology Total Season:** The combined total of preplant, in-crop and preharvest applications of Roundup WeatherMAX can not exceed 5.3 qt/A. The combined total of in-crop and preharvest applications can not exceed 66 oz/A.

*If using another Roundup agricultural herbicide, you must refer to the label booklet or Roundup Ready Corn 2 Technology supplemental label for that brand to determine appropriate use rates. If using Roundup PowerMAX®, application rates are the same as for Roundup WeatherMAX. If using another residual herbicide, follow the labeled use rate instructions applicable to Roundup Ready Corn 2.

**Atrazine may also be used as a residual herbicide in the Roundup Ready Corn 2 System. ***You may apply up to the full residual herbicide labeled rate for corn.

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Roundup Ready 2 Technology

RECOMMENDATIONS FOR MANAGING GLYPHOSATE-RESISTANT WEEDS IN PRODUCTS WITH ROUNDUP READY 2 TECHNOLOGY

Weeds	Recommendations
Glyphosate-Resistant Horseweed (Marestail)	Start clean with a burndown program or tillage. -Tank-mix Roundup agricultural herbicides with 2,4-D, or dicamba, according to the label directions. In-crop, tank-mix 22 ounces per acre of Roundup WeatherMAX with Clarity® (8 to 16 fluid ounces per acre) or 2,4-D (0.5 to 1.0 lb active ingredient per acre) from corn emergence to the 5-leaf stage of corn growth (approximately 8" tall). Or tank-mix 22 ounces per acre of Roundup WeatherMAX with 5 ounces per acre of Status® herbicide when the corn is 4" to 36" tall (V2 to V10). Horseweed should not exceed 6" in height at the time of in-crop application.
Glyphosate-Resistant *Amaranthus* Species **- Palmer Amaranth** **- Waterhemp**	Start clean with a burndown program or tillage. Use a residual herbicide such as Harness® Xtra, Harness Xtra 5.6L, Degree Xtra® or other residual herbicide either preemergence or in-crop for control of *Amaranthus* species. In-crop, tank-mix Roundup WeatherMAX with other herbicides such as 2,4-D, dicamba (Clarity or Banvel®) or Status herbicide to control emerged weeds. Applications of Status herbicide should be made when the corn is between 4" and 36" tall (V2 to V10). Follow all label directions. *Amaranthus* species should not exceed 3" in height at the time of in-crop application.
Glyphosate-Resistant *Ambrosia* Species **- Giant Ragweed** **- Common Ragweed**	Start clean with a burndown program or tillage. Use a residual herbicide such as Harness Xtra, Harness Xtra 5.6L, Degree Xtra or other residual herbicide either preemergence or in-crop for control of *Ambrosia* species. In-crop, tank-mix Roundup WeatherMAX with other herbicides such as 2,4-D, dicamba (Clarity or Banvel) or Status herbicide to control emerged weeds. Applications of Status herbicide should be made when the corn is between 4" and 36" tall (V2 to V10). Follow all label directions. *Ambrosia* species should not exceed 3" in height at the time of in-crop application.
Glyphosate-Resistant Johnsongrass	Start clean with a burndown program or tillage. Use a residual herbicide such as Harness Xtra, Harness Xtra 5.6L, Degree Xtra or other residual herbicide containing atrazine preemergence to reduce the competition from seedling johnsongrass prior to the emergence of corn. In-crop, tankmix Roundup WeatherMAX with a herbicide such as Accent®, Equip™ or Option® for control of emerged weeds including seedling and rhizome johnsongrass. Follow all label directions of tank-mix partners, especially those related to weed size.

In certain areas, Italian ryegrass is known to be resistant to glyphosate. For control recommendations, refer to **www.weedresistancemanagement.com** or call 1-800-ROUNDUP. When approved, supplemental labeling for specific herbicide products can also be viewed on **www.cdms.net** or **www.greenbook.net.**

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Bollgard® and Bollgard II® Cotton

PRODUCT DESCRIPTION

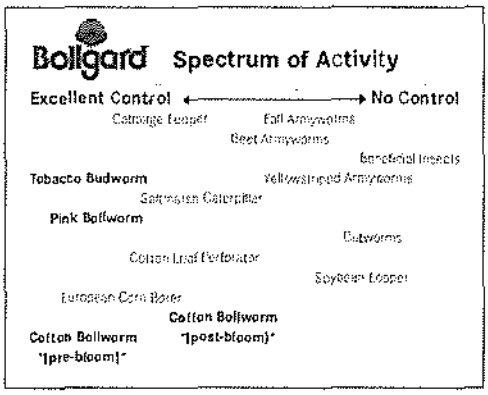
Bollgard® cotton contains an insecticidal protein from *Bacillus thuringiensis*, subsp. *kurstaki* (*B.t.k.*) that protects cotton plants from certain lepidopteran insect pests. Bollgard II® cotton contains two distinct insecticidal proteins from *B.t.k.* that expand the level and spectrum of control and reduce the chance that resistance will develop to the *B.t.k.* insecticidal proteins relative to Bollgard cotton. Specifically, Bollgard provides excellent, season-long control of tobacco budworm and pink bollworm, and suppression of cotton bollworm. When larvae feed on Bollgard cotton plants, these proteins protect the plants from damage by reducing larval survival. Bollgard II cotton normally provides excellent, season-long control of tobacco budworm, pink bollworm, cotton bollworm, fall armyworm, beet armyworm, cabbage and soybean loopers, and other secondary leaf- or fruit-feeding caterpillar pests in cotton (see Spectrum of Activity charts and Manage Target Insects section below). Routine applications of insecticides to control these insects are usually unnecessary when cotton containing Bollgard or Bollgard II cotton is planted.

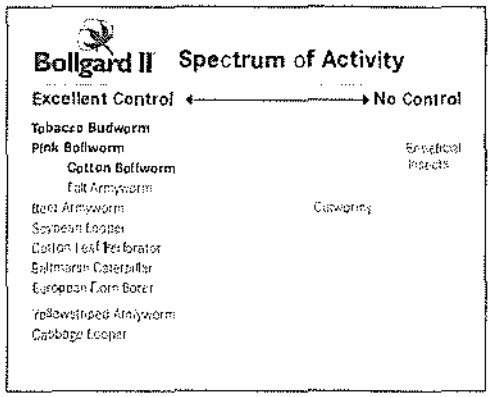
Bollgard and Bollgard II cotton varieties are as safe to the environment, humans and other non-target pests, including beneficial predators and parasites, as other commercial cotton varieties. The insecticidal proteins from *B.t.k.* begin to break down immediately when the plant dies. They do not accumulate in the soil and will not leach into the groundwater. In fact, Bollgard or Bollgard II cotton use should lead to a decrease in broad-spectrum insecticide use, and beneficial insects may increase in the cropping system. Increases in beneficial insects can suppress various cotton pests, further reducing the need for, and application of, insecticides.

BOLLGARD DISCONTINUATION IN 2009

Resistance management is critical to the long-term viability of our technology and the benefits realized by our farmer customers. The move to multiple-gene products, including Bollgard II, offers dual modes of action and increases the longevity of the technology. Monsanto will be working within the EPA's regulatory framework to address the expiration of Bollgard's registration on September 30, 2009, while allowing the sale of any remaining on-hand inventory of Bollgard products up to the registration's expiration.

Any Bollgard cotton seed must be sold and distributed prior to or on September 30, 2009. This deadline will apply to all seed companies who market Bollgard cotton.





NOTE: No planting or sale for commercial planting of Bollgard or Bollgard II cotton is permitted in Hawaii, Puerto Rico, the U.S. Virgin Islands, South of Route 60 (near Tampa) in Florida, and in the following counties in the Texas panhandle: Carson, Oallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman.

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Bollgard

Bollgard II

RECOMMENDED MANAGEMENT PRACTICES

Agronomic Management

As with any cotton variety, using the best agronomic management practices with Bollgard or Bollgard II cotton varieties will yield the greatest benefits. Use varieties, seeding rates, and planting technologies appropriate for each specific area. As much as possible, manage the crop to avoid plant stress.

Manage Target Insects

High populations of cotton bollworm or other insect pests may reach damaging levels that warrant supplemental insecticide applications in Bollgard or Bollgard II cotton. If any cotton insect pest reaches locally established thresholds in Bollgard or Bollgard II cotton, Monsanto recommends the use of appropriate remedial insecticide treatments to ensure desired levels of control.

Fields should be carefully monitored for all pests, including cotton bollworms, to determine the need for remedial insecticide treatments. For target pests, scouting techniques and supplemental treatment decisions should take into account the fact that larvae must hatch and feed before they can be affected by the *B.t.k.* protein(s) in either Bollgard or Bollgard II cotton. Fields should be scouted regularly following periods of heavy or sustained egg lay, especially during bloom, to determine if significant larval survival has occurred. Scouting should include a modified whole plant inspection, including terminals, squares, blooms, bloom tags and small bolls. Larvae greater than 1/4 inch (3- to 4-days old) are generally recognized as survivors that will be difficult-to-control with Bollgard or Bollgard II cotton alone. Apply supplemental insecticides if the frequency of advanced stage larvae or plant damage warrants treatment. Changes to these recommendations may be required under certain circumstances. Consult your local crop advisor or extension specialist for management recommendations in a specific area.

MANAGE NON-TARGET INSECTS

Although Bollgard and Bollgard II cotton varieties will sustain less damage from some of the most troublesome lepidopteran pests, they will not provide protection against non-lepidopteran species. These insects should be monitored and treated when necessary using recommended thresholds and insecticides. If possible, choose insecticides that are least harmful to beneficial insects.

PRACTICE INTEGRATED PEST MANAGEMENT (IPM)

- Employ appropriate scouting techniques and treatment decisions to enhance beneficial insects that can provide some additional insect pest control.
- Manage for appropriate maturity and harvest schedules. Destroy stalks immediately after harvest to avoid regrowth and minimize selection for resistance in late-season infestations.
- Use soil management practices that encourage destruction of over-wintering pupae in cotton containing the Bollgard/Bollgard II traits.

Bollgard II® Cotton Natural Refuge

THE "NATURAL REFUGE" OPTION FOR BOLLGARD II HAS BEEN APPROVED BY THE EPA

Beginning June 1, 2007 farmers choosing to grow varieties containing Bollgard II® are no longer required to plant a structured non-*B.t.k.* cotton refuge associated with their Bollgard II acreage in areas of the United States where the target pests *Heliothis virescens* (tobacco budworm) and *Helicoverpa zea* (cotton bollworm) are prevalent. Monsanto, in conjunction with USDA and university researchers, has been able to demonstrate that sufficient numbers of tobacco budworm and bollworm moths develop naturally from hosts other than cotton to provide the necessary refuge for Bollgard II cotton. The "Natural Refuge" option allows farmers to plant varieties containing Bollgard II and rely on other naturally occurring crops and plants surrounding their Bollgard II fields to serve as the refuge in the following regions:

Farmers may utilize the Natural Refuge option for varieties containing Bollgard II in these states:

ALABAMA
All Counties

ARKANSAS
All Counties

FLORIDA
All Counties EXCEPT:
Areas south of Route 60

GEORGIA
All Counties

KANSAS
All Counties

KENTUCKY
All Counties

LOUISIANA
All Counties

MARYLAND
All Counties

MISSISSIPPI
All Counties

MISSOURI
All Counties

NORTH CAROLINA
All Counties

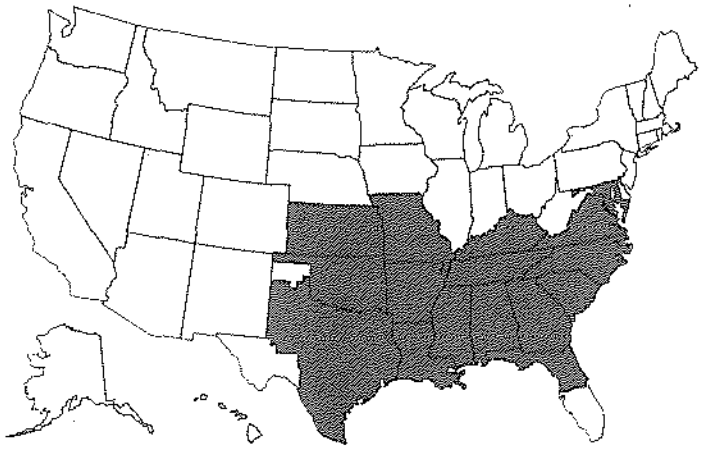
OKLAHOMA
All Counties

SOUTH CAROLINA
All Counties

TENNESSEE
All Counties

VIRGINIA
All Counties

TEXAS
All Counties EXCEPT:
Brewster
Carson
Crane
Crockett
Culberson
Dallam
El Paso
Hansford
Hartley
Hudspeth
Hutchinson
Jeff Davis
Lipscomb
Loving
Moore
Ochiltree
Pecos
Presidio
Reeves
Roberts
Sherman
Terrell
Val Verde
Ward
Winkler



NOTE: Natural Refuge does not apply to cotton varieties that contain the Bollgard® trait. Farmers that grow varieties that contain the Bollgard trait are still required to plant a 5% embedded, 5% unsprayed, or a 20% sprayed non-*B.t.k.* cotton refuge associated with the amount of Bollgard cotton they are growing.

Natural Refuge does not apply to Bollgard II cotton grown in areas where pink bollworm is a pest. These areas include Arizona, California, New Mexico, and in the following counties in Texas: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler. Farmers of Bollgard II cotton in these areas are still required to plant a non-*B.t.k.* cotton refuge. Certain areas where the pink bollworm eradication program is active may allow waivers from this refuge requirement for all *B.t.k.* cotton varieties—check your local or state authorities to determine what is required or allowed in your area.

No planting or sale for commercial planting of Bollgard or Bollgard II cotton is permitted south of Route 60 (near Tampa) in Florida, in Hawaii, Puerto Rico, and the U.S. Virgin Islands, or in the following counties in the Texas panhandle: Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts and Sherman.

Bollgard and Bollgard II Cotton Stewardship

All farmers shall sign the MTSA limited use license application, which provides the terms and conditions for the authorized use of the product. Refer to Stewardship IRM section on page 3 for more information regarding the Bollgard and Bollgard II IRM Monitoring Program.

If Monsanto reasonably believes that a farmer has planted saved cotton seed containing a Monsanto genetic trait, Monsanto will request invoices or otherwise confirm that fields in question have been planted with newly purchased seed. If this information is not provided within 30 days, Monsanto may inspect and test all of the farmer's fields to determine if saved cotton seed has been planted. Any inspections will be performed at a reasonable time and coordinated to accommodate the farmer's schedule.

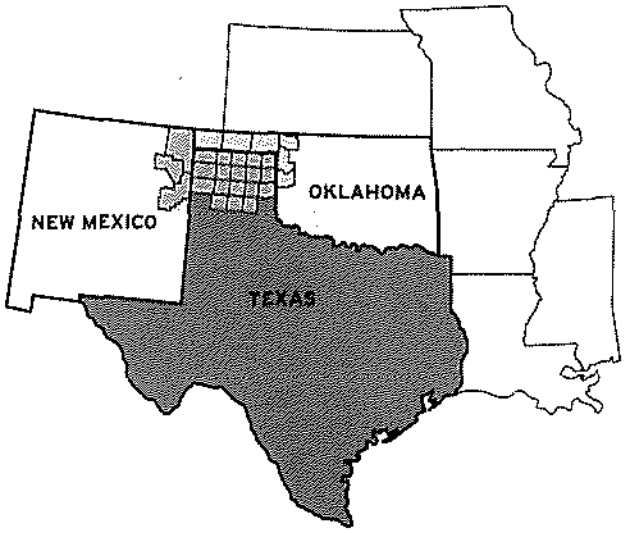
Due to special circumstances, cotton farmers in the counties highlighted in the map **below** will also sign a Seed Use Agreement (SUA) with specific stewardship commitments before they can receive delivery of Bollgard or Bollgard II cotton seed. A SUA will be mailed to licensed farmers in the counties highlighted in the map and can be obtained from your local retailer and/or Monsanto (1-800-768-6387).

By signing the SUA the farmer acknowledges:

- That they will not plant Bollgard or Bollgard II cotton, individually or as part of a stacked product, in any of the following counties in Texas: Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman.

Gin by-products of cotton containing Monsanto's biotech traits, including cottonseed for feed uses, are fully approved for export to Canada, Japan, Mexico, and South Korea. Cottonseed containing Monsanto traits may not be exported for the purpose of planting without a license from Monsanto.

Please see additional Roundup Ready Flex cotton stewardship requirements on page 33.



Areas that require a Seed Use Agreement:

NEW MEXICO
Harding
Quay
Union

OKLAHOMA
Beaver
Cimmarron
Ellis
Harper
Roger Mills
Texas

TEXAS
Armstrong
Carson
Dallam
Donley
Grey
Hansford
Hartley
Hemphill
Hutchinson

Lipscomb
Moore
Ochiltree
Oldham
Potter
Randall
Roberts
Sherman
Wheeler

NOTE: No planting or sale for commercial planting of Bollgard or Bollgard II cotton is permitted in Hawaii, Puerto Rico, the U.S. Virgin Islands, south of Route 60 (near Tampa) in Florida, and in the following counties in the Texas panhandle: Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman.

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Bollgard® and Bollgard II® Cotton Refuge Requirements

INSECT RESISTANCE MANAGEMENT REQUIREMENTS

Lepidopteran cotton pests have demonstrated an ability to develop resistance to many chemical insecticides. As a preemptive measure, Bollgard* and Bollgard II®* cotton varieties must be managed in ways that will retard insect resistance development. These practices are designed to ensure that some lepidopteran populations are not exposed to the *B.t.k.* proteins so they can maintain susceptibility in select populations. To do this, the insects must be provided a refuge that is a food source and that does not contain the *B.t.k.* proteins.

* In selected area, a "Natural Refuge" option has been approved by the EPA. See page 24.

Farmers of Bollgard and Bollgard II cotton must carefully read and follow the insect resistance management requirements for 2009 described in this TUG, the Bollgard and Bollgard II IRM Guides, and any supplemental amendments.

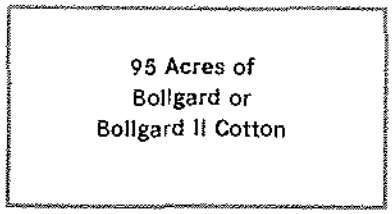
Due to the importance of delaying the development of resistance to Bollgard and Bollgard II cotton, farmers who fail to plant an appropriate refuge where it is required or to manage the refuge properly risk losing access to these products. Please help ensure that *B.t.* technology is preserved by fully implementing the required IRM plan.

Option 1: 5% External Unsprayed Refuge

Plant at least 5 acres of non-*B.t.k.* cotton (as refuge cotton) for every 95 acres of Bollgard or Bollgard II cotton (95% Bollgard or Bollgard II cotton, 5% non-*B.t.k.* refuge). **This refuge may not be treated with any lepidoptera-active insecticide** labeled for the control of tobacco budworm, cotton bollworm or pink bollworm from the appearance of first square through harvest.

EXAMPLE

5% Unsprayed Refuge Option

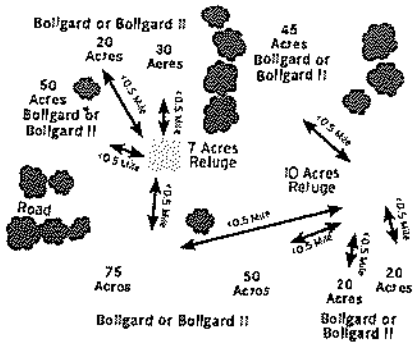


5 Acres of Non-*B.t.k.* Cotton

As required for the 5% embedded refuge option, the unsprayed refuge **must average at least 150 feet wide** (preferably 300 feet wide), and all associated Bollgard or Bollgard II cotton fields **must be within 1/2 mile** (preferably 1/4 mile or closer), field border to field border, of the unsprayed refuge. These requirements apply to all 5% non-*B.t.k.* unsprayed option users regardless of the percentage of cotton acres planted to Bollgard or Bollgard II cotton in that county/parish.

EXAMPLE:

5% Unsprayed Refuge Option–Field Unit



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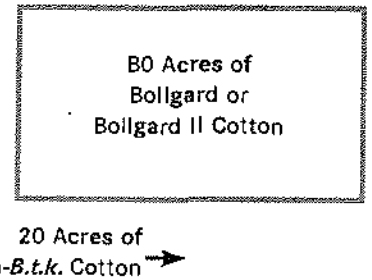
Option 2: 20% External Sprayed Refuge

Plant at least 20 acres of non-*B.t.k.* cotton as a refuge for every 80 acres of Bollgard or Bollgard II cotton (80% Bollgard or Bollgard II cotton, 20% non-*B.t.k.* refuge). This refuge may be treated with any insecticide (excluding foliar *B.t.k.* products). **All Bollgard or Bollgard II cotton fields must be within one mile (preferably within 1/2 mile or closer) of the associated refuge (field border to field border).**

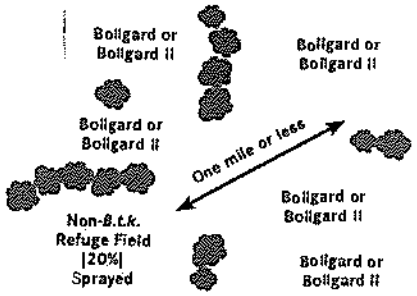
EXAMPLE:
20% Sprayed Refuge Option



To avoid mixing seed in the planting process, be sure to clean all seed out of hoppers when switching from non-*B.t.k.* cotton seed to Bollgard or Bollgard II cotton seed, or vice versa.

In cases where placement of the refuge within one mile of the Bollgard or Bollgard II cotton would be in conflict with state seed production regulations, the farmer must plant the refuge as close to the Bollgard or Bollgard II cotton as allowed.

EXAMPLE:
20% Sprayed Option–Field Unit



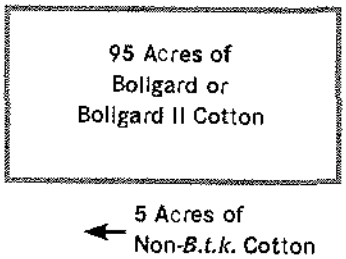
Option 3: 5% Embedded Refuge

Plant at least 5 acres of non-*B.t.k.* cotton (as refuge cotton) for every 95 acres of Bollgard or Bollgard II cotton (95% Bollgard or Bollgard II, 5% non-*B.t.k.* refuge). Plant the refuge cotton embedded as a contiguous block within the Bollgard or Bollgard II cotton field or within the field unit. **The 5% non-*B.t.k.* refuge must average at least 150 feet wide, but preferably 300 feet wide.**

This refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm whenever the entire field is treated. The refuge may not be treated independently of the surrounding Bollgard or Bollgard II cotton field in which this refuge is embedded (or fields within a field unit), except at the pre-squaring cotton stage, when the refuge may be treated with any lepidopteran insecticide to control foliage-feeding caterpillars.

For areas where pink bollworm is the only pest of concern, farmers are allowed to mix individual rows of non-*B.t.k.* cotton with Bollgard or Bollgard II cotton rows to embed their refuge. **These areas include Arizona, California, New Mexico, and the following counties in Texas: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler.** Farmers should plant the refuge cotton with at least one single non-*B.t.k.* cotton row for every 6 to 10 rows of Bollgard or Bollgard II cotton.

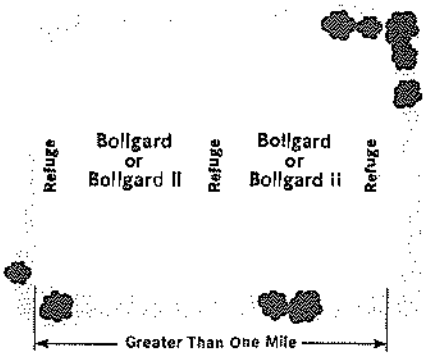
EXAMPLE:
5% Embedded Refuge Option



Bollgard® and Bollgard II® Cotton Refuge Requirements

To implement the 5% embedded option for isolated large field situations, 5% of the field should be planted to a non-*B.t.k.* cotton variety, the rest with Bollgard® or Bollgard II® cotton. For very large fields (length and/or width greater than one mile), place the refuge in more than one location in the field.

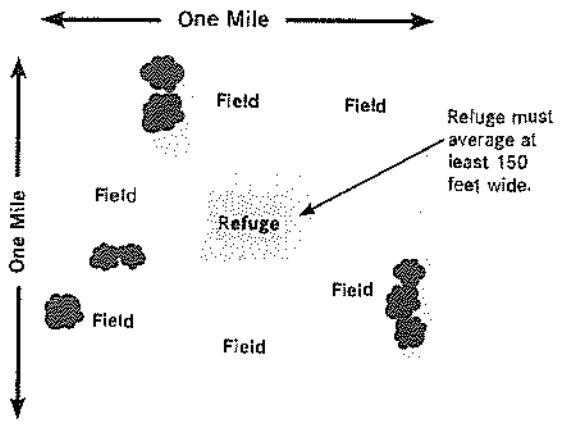
EXAMPLE:
5% Embedded Refuge Option for Very Large Fields



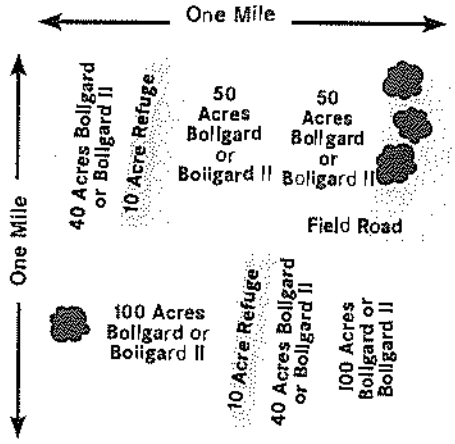
To implement the 5% embedded option for smaller fields or fields that are closely associated, fields can be grouped into "field units" so that one of the smaller fields, or a portion of one of the fields, serves as the "embedded" non-*B.t.k.* refuge. **Any fields contained within a one-mile-squared area can be considered a "field unit."** Likewise, this embedded refuge can be treated with the same insecticide (except foliar *B.t.k.* products) at the same time that ALL of the associated Bollgard or Bollgard II cotton fields within the same field unit are sprayed, but can not be treated with insecticides active on tobacco budworms, cotton bollworms or pink bollworms independently of the associated Bollgard or Bollgard II cotton fields. **The embedded refuge within a field or field unit must average at least 150 feet wide, but preferably 300 feet wide.**

NOTE: The field unit concept for embedded refuge is not allowed in areas where pink bollworm is the only pest of concern. These areas include Arizona, California, New Mexico, and the following counties in Texas: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler.

Field Unit–Definition
Any group of fields that are contained within a one-mile-squared (one mile by one mile) area.



EXAMPLE
5% Embedded Refuge Option for Smaller Fields or Fields That Are Closely Associated



Roundup Ready® Cotton

PRODUCT DESCRIPTION

Roundup Ready® cotton varieties contain in-plant tolerance to Roundup® agricultural herbicides, enabling farmers to make in-crop applications of Roundup WeatherMAX® or Roundup PowerMAX®.

ROUNDUP® AGRICULTURAL OVER-THE-TOP HERBICIDE PRODUCTS

Herbicide products sold by Monsanto for use over the top of Roundup Ready cotton for the 2009 crop season are as follows:

- Roundup WeatherMAX
- Roundup PowerMAX

Do not add additional surfactants to these Roundup agricultural herbicides. Other glyphosate products labeled for use in Roundup Ready cotton may require the addition of surfactants or other additives to optimize performance and can increase the potential for crop injury. Monsanto will label and promote only fully tested brands that do not require additional surfactants and other additives for over-the-top applications.

Roundup Ready cotton is genetically improved to provide tolerance to glyphosate, the active ingredient in Roundup agricultural herbicides. Roundup Ready cotton can receive over-the-top applications of Roundup agricultural herbicides only through the four-leaf stage. With the introduction of Roundup Ready Flex cotton there is the potential for both Roundup Ready cotton and Roundup Ready Flex cotton to be used on a farmer's farm. This creates concern for the safety of Roundup Ready cotton. Monsanto recommends that farmers:

- **Maintain accurate records of which technologies have been planted and where they have been planted.**
- **Communicate field plan with other members of their work force to ensure proper applications for each technology.**
- **Clearly mark fields to indicate which technology has been planted.**

Should you use another glyphosate herbicide, ensure that it has federally approved label instructions for use over Roundup Ready cotton, and the product and the use label for Roundup Ready cotton have been approved by your specific state. Contact the product manufacturers, the local retailers, or the local extension agents for confirmation that the products carry EPA and state approved labeling for this use. MONSANTO DOES NOT MAKE ANY REPRESENTATIONS, WARRANTIES OR RECOMMENDATIONS CONCERNING THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES WHICH ARE LABELED FOR USE OVER ROUNDUP READY COTTON. MONSANTO SPECIFICALLY DENIES ALL RESPONSIBILITY AND DISCLAIMS ANY LIABILITY FOR ANY DAMAGE FROM THE USE OF THESE PRODUCTS IN ROUNDUP READY COTTON. ALL QUESTIONS AND COMPLAINTS CAUSED BY THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES SHOULD BE DIRECTED TO THE SUPPLIER OF THE PRODUCT IN QUESTION.

WEED RESISTANCE MANAGEMENT GUIDELINES

Follow the guidelines below to minimize the risk of developing glyphosate-resistant weed populations in a Roundup Ready cotton system:

- Scout fields before and after each burndown and in-crop application.
- Start clean with a burndown herbicide program or tillage.
- Use the right herbicide product at the right rate and right time.
- Add soil residual herbicide(s) and cultural practices as part of a Roundup Ready cotton weed control program.
- In-crop, apply Roundup WeatherMAX at a minimum of 22 oz/A when weeds are 3" to 6" in height.
- Tank-mix other herbicides with Roundup WeatherMAX if necessary for postemergence weed control.
- Should repeated non-performance occur, report to Monsanto or your local retailer.
- Clean equipment before moving from field to field to minimize the spread of weed seed (as well as nematodes, insects, and other cotton pests).

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Roundup Ready® Cotton

WEED CONTROL RECOMMENDATIONS

Agronomic Principles in Cotton

Weed control in cotton is essential to maximize both fiber yield and quality potential. Cotton is very sensitive to early-season weed competition, which can result in unacceptable stands and/or reduced yield potential. The Roundup Ready® cotton system provides farmers with the right tools to control weeds before they become competitive.

PROGRAM	INSTRUCTIONS	ADDITIONAL INFORMATION
Preplant Burndown	Always start clean by planting into a weed-free field using either tillage or a burndown application. In no-till and reduced-till systems, apply a preplant burndown application of Roundup WeatherMAX®* at 22 to 44 oz/A in a tank-mix with dicamba or 2,4-D. See the dicamba and 2,4-D product label for rates and time intervals required between application and cotton planting. State restrictions may apply.	Early-season weed competition can result in unacceptable stands and/or reduced yield potential. This tank-mix is recommended for control and management of glyphosate-resistant horseweed (marestail, *Conyza sp.*) or other tough-to-control weeds. Burndown application should be made far enough in advance of planting to control existing weeds.
Residual Herbicides	Apply residual herbicide(s) as part of a Roundup Ready cotton weed control program. Use the recommended label rate and timing of the residual herbicide applied. Refer to individual product labels for list of residual herbicides that may be used.	The residual herbicide(s) may be applied as either a preemergence (including preplant incorporated), postemergence, and/or layby application as allowed on the label of the specific product being used.
Over-The-Top through Fourth Leaf	Apply Roundup WeatherMAX over the top from crop emergence through the fourth true-leaf (node) stage (until the fifth true leaf reaches the size of a quarter). Two applications can be made during this period at a maximum rate of 22 oz/A per application. Refer to the "Annual Weeds Rate Table" in the Roundup WeatherMAX label for rate recommendations for specific annual weeds.	In-crop over-the-top applications must be at least 10 days apart and the cotton must have at least two nodes of incremental growth between applications. Care should be taken to record growth stage at first application. In situations where the potential for weed infestations is high (including perennial weeds), make the first application early enough to allow a second application before cotton exceeds the fourth true-leaf stage. Over-the-top applications after the fourth true-leaf stage can result in boll loss, delayed maturity, and/or yield loss.
Selective Equipment	After the fourth true-leaf stage through layby, Roundup WeatherMAX may be applied using precision post-directed or hooded sprayers which direct the spray to the base of the cotton plant. Two post-directed applications can be made during this period at a maximum rate of 22 oz/A per application.	Place nozzles in a low horizontal position to permit spray pattern to overlap in the row while contact of spray solution with cotton leaves should be avoided to the maximum extent possible. Excessive foliar contact can result in boll loss, delayed maturity, and/or yield loss. There must be two nodes of growth and at least 10 days between applications.
Preharvest Over-The-Top Applications	Before harvest and after cotton reaches 20 percent boll-crack, if needed, apply up to 44 oz/A of Roundup WeatherMAX. This treatment is effective in controlling late-season perennial weeds and can improve harvest efficiency.	Applications must be made at least 7 days prior to harvest. Roundup agricultural herbicides are not effective for preharvest cotton regrowth in Roundup Ready cotton. Do not apply Roundup agricultural herbicides preharvest to crops grown for seed under contract at an authorized cotton seed company.

Roundup Ready cotton has excellent vegetative tolerance to Roundup WeatherMAX allowing early-season over-the-top applications. Incomplete reproductive tolerance requires that applications after the 4-leaf (node) stage be properly post-directed.

ATTENTION: Use of Roundup agricultural herbicides in accordance with label directions is expected to result in normal growth of Roundup Ready cotton, however, various environmental conditions, agronomic practices, and other factors make it impossible to eliminate all risks associated with the product, even when applications are made in conformance with the label specifications. In some cases, these factors can result in boll loss, delayed maturity, and/or yield loss.

*If using another Roundup agricultural herbicide, you must refer to the label booklet or Roundup Ready cotton supplemental label for that brand to determine appropriate use rates. If using Roundup PowerMAX®, application rates are the same as for Roundup WeatherMAX.

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Roundup Ready Cotton

RECOMMENDATIONS FOR MANAGING GLYPHOSATE-RESISTANT WEEDS IN ROUNDUP READY COTTON

Glyphosate-Resistant (Horseweed) Marestail	Start clean with a burndown herbicide program or tillage. -Tank-mix Roundup agricultural herbicides with dicamba or 2,4-D (consult label for plant back timing). If you have dense stands of marestail, use a preplant residual herbicide at the recommended rate and timing, such as diuron (Direx®) or flumioxazin (Valor®). Use Roundup WeatherMAX® in-crop, as needed, at a minimum of 22 oz/A to control other weeds. In-crop, if applying post-directed to glyphosate-resistant marestail, Roundup WeatherMAX can be tank-mixed with other herbicides, such as diuron or MSMA. Horseweed should not exceed 6" in height at the time of in-crop application.
Glyphosate-Resistant *Amaranthus* Species **- Palmer Amaranth** **- Waterhemp**	Start clean with a burndown herbicide program or tillage. Apply a preemergence residual herbicide such as pendimethalin (Prowl®) plus fluometuron or fomesafen (Reflex®) for control of *Amaranthus* species. In-crop, tank-mix Roundup WeatherMAX at 22 oz/A with metolachlor before *Amaranthus* species emerges. Use Roundup WeatherMAX in-crop, as needed, at a minimum of 22 oz/A to control other weeds. A post-directed application of Roundup WeatherMAX tank-mixed with MSMA and a residual such as diuron (Direx) or flumioxazin (Valor) should be made to control *Amaranthus* species 3" or smaller in height and prevent additional flushes.
Glyphosate-Resistant *Ambrosia* Species **- Giant Ragweed** **- Common Ragweed**	Start clean with a burndown herbicide program or tillage. Apply a preemergence residual herbicide such as pendimethalin (Prowl) plus fluometuron or fomesafen (Reflex) for control of *Ambrosia* species. In-crop, tank-mix Roundup WeatherMAX at 22 oz/A with metolachlor before *Ambrosia* species emerges. Use Roundup WeatherMAX in-crop, as needed, at a minimum of 22 oz/A to control other weeds. A post-directed application of Roundup WeatherMAX tank-mixed with MSMA and a residual such as diuron (Direx) or flumioxazin (Valor) should be made to control *Ambrosia* species 3" or smaller in height and prevent additional flushes.
Glyphosate-Resistant Johnsongrass	Start clean with a burndown herbicide or tillage. Preplant incorporate a residual herbicide such as pendimethalin or trifluralin for control or suppression of seedling johnsongrass. Apply Roundup WeatherMAX in a tankmix with herbicides such as SelectMAX®, Assure® II or Poast Plus for the control of emerged weeds including seedling and rhizome johnsongrass. Follow all label directions of tank-mix partners, especially those related to weed size.

In certain areas, Italian ryegrass is known to be resistant to glyphosate. For control recommendations, refer to **www.weedresistancemanagement.com** or call 1-800-ROUNDUP. When approved, supplemental labeling for specific herbicide products can also be viewed on **www.cdms.net** or **www.greenbook.net.**

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Roundup Ready® Flex Cotton

PRODUCT DESCRIPTION

Roundup Ready® Flex cotton varieties possess improved reproductive tolerance to Roundup® agricultural herbicides. This technology gives farmers the opportunity to make over-the-top broadcast applications of labeled Roundup agricultural herbicides, as listed below, from crop emergence up to seven (7) days prior to harvest.

ROUNDUP® AGRICULTURAL OVER-THE-TOP HERBICIDE PRODUCTS

Herbicide products sold by Monsanto for use over the top of Roundup Ready Flex cotton for the 2009 crop season include:

- Roundup WeatherMAX®
- Roundup PowerMAX®

Do not add additional surfactants and/or products containing surfactants to these Roundup agricultural herbicides. Other glyphosate products labeled for use in Roundup Ready Flex cotton may require the addition of surfactants or other additives to optimize performance that may increase the potential for crop injury. Monsanto will label and promote only fully tested brands that do not require surfactants and other additives for over-the-top applications.

Should you choose to use another glyphosate herbicide, ensure that it has federally approved label instructions for use over Roundup Ready Flex cotton, and the product and the use label for Roundup Ready Flex cotton have been approved by your specific state. Contact the product manufacturers, the local retailers, or the local extension agents for confirmation that the products carry EPA and state approved labeling for this use. MONSANTO DOES NOT MAKE ANY REPRESENTATIONS, WARRANTIES OR RECOMMENDATIONS CONCERNING THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES WHICH ARE LABELED FOR USE OVER ROUNDUP READY FLEX COTTON. MONSANTO SPECIFICALLY DENIES ALL RESPONSIBILITY AND DISCLAIMS ANY LIABILITY FOR ANY DAMAGE FROM THE USE OF THESE PRODUCTS IN ROUNDUP READY FLEX COTTON. ALL QUESTIONS AND COMPLAINTS CAUSED BY THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES SHOULD BE DIRECTED TO THE SUPPLIER OF THE PRODUCT IN QUESTION.

CROP SAFETY OF OVER-THE-TOP GLYPHOSATE APPLICATIONS TO ROUNDUP READY FLEX COTTON

Monsanto has determined that a certain combination of components in glyphosate formulations have the potential to cause leaf injury when applied during later stages of crop growth. Roundup WeatherMAX and Roundup PowerMAX are the only Roundup agricultural herbicides labeled and approved for new labeled uses over the top of Roundup Ready Flex cotton. Leaf injury may occur if the products are not used according to the product label, used at higher than recommended rates, or if overlap of spray occurs in the field. *Farmers should confirm that any glyphosate formulation to be used on Roundup Ready Flex cotton has been labeled for Roundup Ready Flex cotton and also that it has been tested to demonstrate crop safety.*

WEED RESISTANCE MANAGEMENT GUIDELINES

Follow the guidelines below to minimize the risk of developing weed resistance in a Roundup Ready Flex cotton system:

- Scout fields before and after each burndown and in-crop application.
- Start clean with a burndown herbicide program or tillage.
- Use the right herbicide product at the right rate and right time.
- Add soil residual herbicide(s) and cultural practices as part of a Roundup Ready Flex cotton weed control program.
- In-crop, apply Roundup WeatherMAX at a minimum of 22 oz/A when weeds are 3" to 6" in height.
- Tank-mix other herbicides with Roundup WeatherMAX if necessary for postemergence weed control.
- Should repeated non-performance occur, report to Monsanto or your local retailer.
- Clean equipment before moving from field to field to minimize the spread of weed seed (as well as nematodes, insects, and other cotton pests).

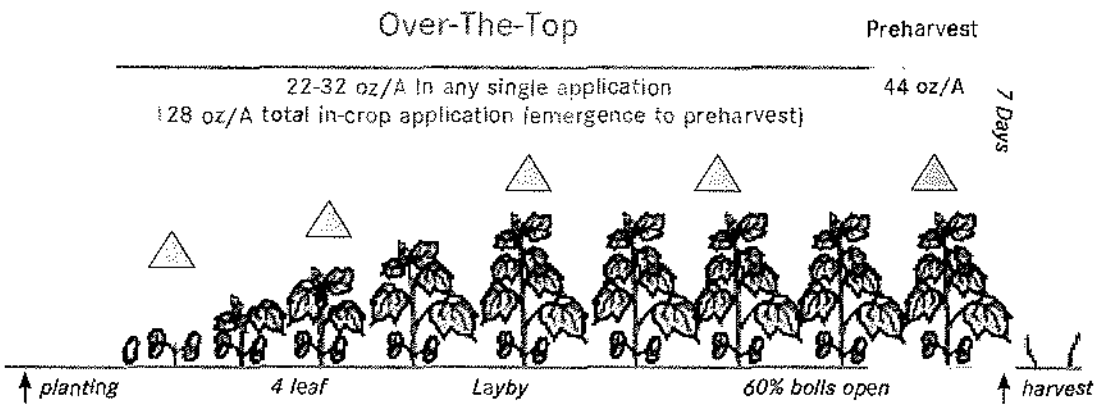
Roundup Ready Flex Cotton

IN-CROP APPLICATION OF ROUNDUP WEATHERMAX® AND ROUNDUP POWERMAX®

- May be applied over the top and/or in-crop, from crop emergence up to 7 days prior to harvest.
- A maximum rate of 32 oz/A per application may be applied using ground application equipment while the maximum is 22 oz/A per application by air.
- There are no growth or timing restrictions for sequential applications.
- Four (4) quarts/A is the total in-crop volume allowed from emergence to 60 percent open bolls.
- A maximum total volume of 44 oz/A may be applied between layby and 60 percent open bolls.
- Post-directed equipment may be used to achieve more thorough spray coverage of weeds or if herbicides not labeled for over-the-top application will be tank-mixed with Roundup WeatherMAX or Roundup PowerMAX.

PREHARVEST APPLICATIONS

- Up to 44 oz/A may be applied after cotton reaches 60 percent open bolls and before harvest, if needed.
- Applications must be made at least 7 days prior to harvest.



CROP SAFETY OF OVER-THE-TOP GLYPHOSATE APPLICATIONS TO ROUNDUP READY FLEX COTTON

Monsanto has determined that a combination of components in glyphosate formulations have the potential to cause leaf injury when applied during later stages of crop growth. Roundup WeatherMAX and Roundup PowerMAX are the only Roundup agricultural herbicides labeled and approved for new labeled uses over the top of Roundup Ready Flex cotton. Leaf injury may occur if the products are not used according to the product label, used at higher than recommended rates or if overlap of spray occurs in the field. *Farmers should confirm that any glyphosate formulation to be used on Roundup Ready Flex cotton has been labeled for Roundup Ready Flex cotton and also that it has been tested to demonstrate crop safety.*

ROUNDUP READY FLEX COTTON SEED STEWARDSHIP

Roundup Ready Flex cotton and Bollgard II with Roundup Ready Flex cotton have full regulatory clearance in the United States, but do not have full import approval in all export markets. Processed fractions from these products, including linters, oil, meal, cottonseed and gin trash must not be exported without all necessary approvals in the importing country. It is a violation of national and international law to move material containing biotech traits across boundaries into nations where import is not permitted.

Roundup Ready® Flex Cotton

WEED CONTROL RECOMMENDATIONS

Agronomic Principles in Cotton

Weed control in cotton is essential to maximize both fiber yield and quality potential. Cotton is very sensitive to early-season weed competition which can result in unacceptable stands and/or reduced yield potential.

The Roundup Ready® Flex cotton system, with improved reproductive tolerance to Roundup® agricultural herbicides, provides farmers with the right tools to control weeds.

PROGRAM	INSTRUCTIONS	ADDITIONAL INFORMATION
Preplant Burndown	Always start clean by planting into a weed-free field using either tillage or a burndown application.	Early-season weed competition can result in unacceptable stands and/or reduced yield potential.
	In no-till and reduced-till systems, apply a preplant burndown application of Roundup WeatherMAX®* at 22 to 44 oz/A in a tank-mix with dicamba or 2,4-D.	This tank-mix is recommended for control and management of glyphosate-resistant horseweed (marestail, *Conyza sp.*) or other tough-to-control weeds.
	See the dicamba and 2,4-D product label for rates and time intervals required between application and cotton planting. State restrictions may apply.	Burndown application should be made far enough in advance of planting to control existing weeds.
Residual Herbicides	Apply residual herbicide(s) as part of a Roundup Ready Flex cotton weed control program. Use the recommended label rate and timing of the residual herbicide applied. Refer to individual product labels for list of residual herbicides that may be used.	The residual herbicide(s) may be applied as either a preemergence (including preplant incorporated), postemergence, and/or layby application as allowed on the label of the specific product being used.
In-Crop Weed Control	Target the first application of Roundup WeatherMAX on 1-2 leaf cotton when weeds are small.	Early-season weed competition can reduce yield potential in cotton.
	Apply a minimum of 22 oz/A of Roundup WeatherMAX in-crop.	Select timing of application based on the most difficult to control weed species in your field.
	The need for sequential applications of Roundup WeatherMAX will depend upon the occurrence of subsequent weed flushes.	Post-direct or hooded sprayers can be used to achieve more thorough spray coverage on weeds.
	Refer to the "Annual Weeds Rate Table" in the Roundup WeatherMAX label booklet for rate recommendations for specific annual weeds.	
Preharvest Over-The-Top Applications	Before harvest and after cotton reaches 60 percent open bolls, if needed, apply up to 44 oz/A of Roundup WeatherMAX.	Applications must be made at least 7 days prior to harvest.
	This treatment is effective in controlling late-season perennial weeds.	Roundup agricultural herbicides are not effective for preharvest cotton regrowth in Roundup Ready Flex cotton.

* The maximum volume of Roundup WeatherMAX and Roundup PowerMAX® that may be used in a single season is 5.3 quarts per acre.

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Roundup Ready Flex Cotton

RECOMMENDATIONS FOR MANAGING GLYPHOSATE-RESISTANT WEEDS IN ROUNDUP READY FLEX COTTON

Weeds	Recommendations for Control
Glyphosate-Resistant (Horseweed) Marestail	Start clean with a burndown herbicide program or tillage. -Tank-mix Roundup® agricultural herbicides with dicamba or 2,4-D (consult label for plant back timing). If you have dense stands of marestail, use a preplant residual herbicide at the recommended rate and timing, such as diuron (Direx®) or flumioxazin (Valor®). Use Roundup WeatherMAX® in-crop, as needed, at a minimum of 22 oz/A to control other weeds. In-crop, if applying post-directed to glyphosate-resistant marestail, Roundup WeatherMAX can be tank-mixed with other herbicides, such as diuron or MSMA. Horseweed should not exceed 6" in height at the time of in-crop application.
Glyphosate-Resistant *Amaranthus* Species **- Palmer Amaranth** **- Waterhemp**	Start clean with a burndown herbicide program or tillage. Apply a preemergence residual herbicide such as pendimethalin (Prowl®) plus fluometuron or fomesafen (Reflex®) for control of *Amaranthus* species. In-crop, tank-mix Roundup WeatherMAX at 22 oz/A with metolachlor before *Amaranthus* species emerges. Use Roundup WeatherMAX in-crop, as needed, at a minimum of 22 oz/A to control other weeds. A post-directed application of Roundup WeatherMAX tank-mixed with MSMA and a residual such as diuron (Direx) or flumioxazin (Valor) should be made to control *Amaranthus* species 3" or smaller in height and prevent additional flushes.
Glyphosate-Resistant *Ambrosia* Species **- Giant Ragweed** **- Common Ragweed**	Start clean with a burndown herbicide program or tillage. Apply a preemergence residual herbicide such as pendimethalin (Prowl) plus fluometuron or fomesafen (Reflex) for control of *Ambrosia* species. In-crop, tank-mix Roundup WeatherMAX at 22 oz/A with metolachlor before *Ambrosia* species emerges. Use Roundup WeatherMAX in-crop, as needed, at a minimum of 22 oz/A to control other weeds. A post-directed application of Roundup WeatherMAX tank-mixed with MSMA and a residual such as diuron (Direx) or flumioxazin (Valor) should be made to control *Ambrosia* species 3" or smaller in height and prevent additional flushes.
Glyphosate-Resistant Johnsongrass	Start clean with a burndown herbicide or tillage. Preplant incorporate a residual herbicide such as pendimethalin or trifluralin for control or suppression of seedling johnsongrass. Apply Roundup WeatherMAX in a tankmix with herbicides such as SelectMAX®, Assure® II or Poast Plus for the control of emerged weeds including seedling and rhizome johnsongrass. Follow all label directions of tank-mix partners, especially those related to weed size.

In certain areas, Italian ryegrass is known to be resistant to glyphosate. For control recommendations, refer to **www.weedresistancemanagement.com** or call 1-800-ROUNDUP. When approved, supplemental labeling for specific herbicide products can also be viewed on **www.cdms.net** or **www.greenbook.net**.

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Bollgard® with Roundup Ready® Cotton and Bollgard II® with Roundup Ready® Cotton

PRODUCT DESCRIPTION

Bollgard® with Roundup Ready® and Bollgard II® with Roundup Ready cotton varieties offer farmers all the benefits of both insect protection and glyphosate tolerance combined in one crop. These varieties exhibit the same insect protection qualities as Bollgard cotton and Bollgard II cotton and enable farmers to make in-crop applications of Roundup WeatherMAX® or Roundup PowerMAX®.

RECOMMENDED MANAGEMENT PRACTICES

Managing Bollgard with Roundup Ready cotton and Bollgard II with Roundup Ready cotton requires a farmer to follow the recommended management practices associated with cotton containing each individual trait.

Farmers of Bollgard with Roundup Ready cotton and Bollgard II with Roundup Ready cotton varieties must follow the same guidelines for establishing required refuge options, practicing IPM and managing target and non-target pests as described for Bollgard and Bollgard II cotton on pages 23-24 of this guide or refer to the current Bollgard and Bollgard II IRM Guide.

Farmers of Bollgard with Roundup Ready cotton and Bollgard II with Roundup Ready cotton varieties must also follow the same guidelines for weed resistance management, recommendations for weed control, and recommendations for managing glyphosate-resistant weeds as described for Roundup Ready cotton on pages 29-31 of this guide.

Bollgard II with Roundup Ready Flex Cotton

PRODUCT DESCRIPTION

Bollgard II with Roundup Ready Flex cotton varieties offer farmers all the benefits of both insect protection and glyphosate tolerance combined in one crop. These varieties exhibit the same insect protection qualities as Bollgard II cotton and are tolerant to over-the-top applications of Roundup WeatherMAX and Roundup PowerMAX, as listed below.

RECOMMENDED MANAGEMENT PRACTICES

Managing Bollgard II with Roundup Ready Flex cotton requires a farmer to follow the recommended management practices associated with cotton containing each individual trait.

Farmers of Bollgard II with Roundup Ready Flex cotton varieties must follow the same guidelines for establishing required refuge options, practicing Integrated Pest Management and managing target and non-target pests as described for Bollgard II cotton on pages 23-25 of this guide and in the current Bollgard/ Bollgard II IRM Guide.

Farmers of Bollgard II with Roundup Ready Flex cotton varieties must also follow the same guidelines for weed resistance management, in-crop and preharvest applications of Roundup WeatherMAX and Roundup PowerMAX, weed control recommendations, and recommendations for managing glyphosate-resistant weeds as described for Roundup Ready Flex cotton on page 35 of this guide.

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Roundup Ready Soybeans

PRODUCT DESCRIPTION

Roundup Ready Soybean varieties contain in-plant tolerance to Roundup agricultural herbicides, enabling farmers to spray labeled Roundup agricultural herbicides over the top from emergence (cracking) through flowering (R2 stage soybeans) for unsurpassed weed control, proven crop safety and maximum yield potential. R2 stage soybeans end when a pod 5 millimeters (3/16") long at one of the four uppermost nodes appears on the main stem along with a fully developed leaf (R3 stage).

ROUNDUP AGRICULTURAL OVER-THE-TOP HERBICIDE PRODUCTS

Herbicide products sold by Monsanto for use over the top of Roundup Ready Soybeans for the 2009 crop season are as follows:

- Roundup WeatherMAX
- Roundup PowerMAX

Certain products referred to above may not be labeled for this application in your specific state. Please contact the manufacturer of this product, the local retailer, or the local extension agent for confirmation that this is an approved application.

For complete information about the use of Roundup agricultural herbicides over the top of Roundup Ready Soybeans, refer to the appropriate product's label booklet.

You may use another glyphosate herbicide, but only if it has federally approved label instructions for use over Roundup Ready Soybeans, and the product and the use label for Roundup Ready Soybeans have been approved by your specific state. Contact the product manufacturers, the local retailers, or the local extension agents for confirmation that the products carry EPA and state approved labeling for this use. MONSANTO DOES NOT MAKE ANY REPRESENTATIONS, WARRANTIES OR RECOMMENDATIONS CONCERNING THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES WHICH ARE LABELED FOR USE OVER ROUNDUP READY SOYBEANS. MONSANTO SPECIFICALLY DENIES ALL RESPONSIBILITY AND DISCLAIMS ANY LIABILITY FOR ANY DAMAGE FROM THE USE OF THESE PRODUCTS IN ROUNDUP READY SOYBEANS. ALL QUESTIONS AND COMPLAINTS CAUSED BY THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES SHOULD BE DIRECTED TO THE SUPPLIER OF THE PRODUCT IN QUESTION.

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Roundup Ready® Soybeans

WEED CONTROL RECOMMENDATIONS

Agronomic Principles in Soybeans

Starting clean with a weed-free field and making timely post-emergence in-crop applications is critical to obtaining excellent weed control and maximum yield potential. The Roundup Ready® Soybean system provides the flexibility to use the herbicide tools necessary to control weeds at planting and in-crop. Failure to control weeds with the right rate, at the right time, and with the right product, can lead to increased weed competition and the potential for decreased yield.

PROGRAM	INSTRUCTIONS AND USE RATES	ADDITIONAL INFORMATION
Preplant Burndown	To start clean in no-till systems, apply a burndown application of Roundup WeatherMAX®* at 22 to 44 oz/A before planting. See the label for appropriate rates by weed species. For control and management of glyphosate-resistant horseweed (marestail, *Conyza sp.*) or other difficult-to-control weeds present at burndown, apply 22 oz/A of Roundup WeatherMAX in a tank-mix with 1 to 2 pt/A 2,4-D. Make applications 7 to 30 days before planting and before horseweed reaches 6" in height.	Always start with a weed-free field. In no-till and reduced-till systems, apply a Roundup WeatherMAX* burndown application to control existing weeds before planting. Adding 2,4-D in the burndown can significantly reduce broadleaf weed pressure at post-emergence timing. Read the 2,4-D product label for time intervals required between application and soybean planting.
Residual Herbicide Plus Roundup WeatherMAX	Use the recommended label rate of a soil-applied residual herbicide applied preemergence to soybeans as defined in the individual product's labeling. The residual product may be tank-mixed with Roundup WeatherMAX at burndown. Refer to individual product labels for list of residual herbicides that may be used. Follow with 22 oz/A Roundup WeatherMAX in-crop when weeds are 2" to 8" tall. Refer to the "Annual Weeds Rate Table" in the Roundup WeatherMAX label for rate recommendations for specific annual weeds. Crop rotation following Roundup Ready Soybeans is strongly encouraged. Use of a residual herbicide is encouraged especially if the cropping system is a continuous Roundup Ready Soybean system.	A residual program is encouraged when agronomic conditions favor the practice. Reducing Roundup WeatherMAX rate when tank-mixing with a residual or use of premixes utilizing a reduced rate of glyphosate (such as Extreme®) is not recommended. If the in-crop application is delayed and weeds are larger, apply a higher rate of Roundup WeatherMAX.
Roundup WeatherMAX	Apply a minimum of 22 oz/A of Roundup WeatherMAX* in-crop when weeds are 2" to 8" tall. Refer to the "Annual Weeds Rate Table" in the Roundup WeatherMAX label for rate recommendations for specific annual weeds. Choose the rate to control the most difficult-to-control weed in your field. A sequential application of this product may be required to control new flushes of weeds in the Roundup Ready Soybean crop. If a sequential application is necessary, apply 16 to 22 oz/A Roundup WeatherMAX* when weeds are 3" to 6" tall.	In-crop application of Roundup WeatherMAX provides control of labeled weeds. For best results, apply 3 to 4 weeks after planting or when weeds are 4" to 8" tall. If initial application is delayed and weeds are larger, apply a higher labeled rate of Roundup WeatherMAX.
Glyphosate-Tolerant Volunteer Corn	Tank-mix Roundup WeatherMAX with 6 to 12 oz/A of Select Max™ and apply to 4" to 36" glyphosate-tolerant volunteer corn.	Choose your Roundup WeatherMAX rate based on the weed species and size listed in the "Annual Weeds Rate Table" of the Roundup WeatherMAX Label.
Maximum Use Rates for Roundup WeatherMAX	**In-Crop:** - 44 oz/A per single application - 44 oz/A during flowering - 64 oz/A emergence through flowering (R2 stage soybeans) **Preharvest:** - 22 oz/A application	**Total Season:** The combined total of preplant, in-crop and preharvest applications of Roundup WeatherMAX can not exceed 5.3 qt/A. The combined total of in-crop and preharvest applications can not exceed 64 oz/A.

*If using another Roundup agricultural herbicide, you must refer to the label booklet or Roundup Ready Soybean supplemental label for that brand to determine appropriate use rates. If using Roundup PowerMAX, application rates are the same as for Roundup WeatherMAX.

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Roundup Ready Soybeans

WEED CONTROL RECOMMENDATIONS

KEY WEEDS	INSTRUCTIONS AND USE RATES	ADDITIONAL INFORMATION
Weeds that Tend to Have Multiple Emergence Events	Where dense stands of weed species such as common lambsquarters, tall and common waterhemp, *Palmer Amaranth*, redroot pigweed, common ragweed, and giant ragweed are expected, the following agronomic practices are recommended: • Start clean with tillage or burndown in no-till and reduced till systems. Include 2,4-D in the burndown. • Plant soybeans in narrow rows (<20"). • Use a pre-plant residual herbicide. • Use the right rate of Roundup WeatherMAX at the right time (proper weed size).	Weeds such as lambsquarters, waterhemp, pigweed, and giant ragweed tend to emerge throughout the season. Sequential Roundup WeatherMAX applications or the addition of a soil residual herbicide may be required for control of subsequent weed flushes.
Difficult-to-Control Weeds	Black nightshade, velvetleaf, waterhemp, morningglory, Florida pusley, giant ragweed, Pennsylvania smartweed, groundcherry, hemp sesbania and spurred anoda are difficult-to-control weeds. Please refer to the Roundup agricultural herbicide label for specific rates and weed sizes for control of these weeds.	These weed species require special attention be paid to Roundup WeatherMAX rate and application timing (proper weed size) to obtain excellent weed control. A sequential application may be required if a new weed flush occurs, especially in soybeans planted in wide rows (>20").
Perennial Weeds	An in-crop application of 22 to 44 oz/A of Roundup WeatherMAX* will provide suppression and/or control of nutsedge and perennial weeds like Canada thistle, field bindweed, hemp dogbane, horsenettle, johnsongrass, milkweed, quackgrass, etc.	For additional information on perennial weeds, see the "Perennial Weeds Rate Table" in the label booklet for Roundup WeatherMAX. For best control, allow perennials to achieve at least 6" or more of growth before spraying.

*If using another Roundup® agricultural herbicide, you must refer to the label booklet or Roundup Ready Soybean supplemental label for that brand to determine appropriate use rates. If using Roundup PowerMAX®, application rates are the same as for Roundup WeatherMAX.

WEED RESISTANCE MANAGEMENT GUIDELINES

Follow the guidelines below to minimize the risk of developing glyphosate-resistant weed populations in a Roundup Ready Soybean system:

- Crop rotation is strongly encouraged.
- Scout fields before and after each burndown and in-crop application.
- Start clean with a burndown herbicide or tillage.
  - Tank-mix with 2,4-D to control glyphosate-resistant marestail or other tough-to-control broadleaf weeds.
- Use the recommended label rate of a soil-applied residual herbicide such as INTRRO®, Valor®, Valor XLT® or Gangster®.
- In-crop, apply Roundup WeatherMAX at a minimum of 22 oz/A before weeds exceed 8" in height.
- If an additional flush of weeds occurs, a sequential application of Roundup WeatherMAX at 22 oz/A may be needed before weeds exceed 6" in height.
- Refer to individual product labels for a list of recommended tank-mix partners.
- Refer to individual product label for list of recommended tank-mix partners.
- Clean equipment before moving from field to field to minimize the spread of weed seed.
- Report repeated non-performance to Monsanto or your local retailer.

Roundup Ready® Soybeans

RECOMMENDATIONS FOR MANAGING GLYPHOSATE-RESISTANT WEEDS IN ROUNDUP READY SOYBEANS

WEEDS	INSTRUCTIONS AND USE RATES
Glyphosate-Resistant Horseweed (Marestail)	**Preplant:** Apply a tank-mixture of 22 oz/A Roundup WeatherMAX® with 1 pt/A 2,4-D before horseweed exceeds 6" in height. See the 2,4-D product label for time intervals required between application and planting. **In-crop:** It is strongly encouraged that horseweed should be controlled prior to planting using recommended preplant burndown treatments. In-crop, apply a tank-mixture of 22 oz/A Roundup WeatherMAX with 0.3 oz/A FirstRate®. This treatment should be used as a salvage treatment only for a horseweed infestation that was not controlled preplant. Application should be made between full emergence of the first trifoliate leaf and 50 percent flowering stage of soybeans. At the time of treatment, horseweed should not exceed 6" in height.
Glyphosate-Resistant *Amaranthus* Species **- Palmer Amaranth** **- Waterhemp**	**Preplant:** Apply a tank-mix of 22 oz/A Roundup WeatherMAX with a preemergence residual herbicide such as alachlor (INTRRO®), flumioxazin (Valor®) or another residual herbicide for preemergence control of *Amaranthus* species. 2,4-D may be added to the tank-mix to help control emerged *Amaranthus* species and other broadleaf weeds preplant only. Follow label instructions regarding application timing relative to soybean planting. **In-crop:** It is strongly encouraged that a preemergence residual product be used to control *Amaranthus* species prior to emergence. If there is emerged *Amaranthus* in-crop, apply a tank-mixture of 22 oz/A Roundup WeatherMAX with a postemergence product with activity on *Amaranthus* such as lactofen (Cobra®), fomesafen (Flexstar®) or cloransulam (FirstRate). Applications should be made on emerged *Amaranthus* that does not exceed 3" in height. Read and follow all product label instructions. It is likely that visual soybean injury will occur with these tank-mixtures.
Glyphosate-Resistant *Ambrosia* Species **- Giant Ragweed** **- Common Ragweed**	**Preplant:** Apply a tank-mix of 22 oz/A Roundup WeatherMAX with a preemergence residual herbicide such as cloransulam (FirstRate) or cloransulam + flumioxazin (Gangster®) or another residual herbicide for preemergence control of *Ambrosia* species. 2,4-D may be added to the tank-mix to help control emerged *Ambrosia* species and other broadleaf weeds preplant only. Follow label instructions regarding application timing relative to soybean planting. **In-crop:** It is strongly encouraged that a preemergence residual product be used to control *Ambrosia* species prior to emergence. If there is emerged *Ambrosia* in-crop, apply a tank-mixture of 22 oz/A Roundup WeatherMAX with a postemergence product with activity on *Ambrosia* such as lactofen (Cobra) or fomesafen (Flexstar). Applications should be made on emerged *Ambrosia* that does not exceed 3" in height. Read and follow all product label instructions. It is likely that visual soybean injury will occur with these tank-mixtures.
Glyphosate-Resistant Johnsongrass	Start clean with a burndown herbicide or tillage. Preplant incorporate a residual herbicide such as pendimethalin or trifluralin for control or suppression of seedling johnsongrass. Apply Roundup WeatherMAX in a tankmix with herbicides such as SelectMAX®, Assure® II or Poast Plus for the control of emerged weeds including seedling and rhizome johnsongrass. Follow all label directions of tank-mix partners, especially those related to weed size.

In certain areas, Italian ryegrass is known to be resistant to glyphosate. For control recommendations, refer to **www.weedresistancemanagement.com** or call 1-800-ROUNDUP. When approved, supplemental labeling for specific herbicide products can also be viewed on **www.cdms.net** or **www.greenbook.net.**

Roundup Ready Alfalfa

PRODUCT DESCRIPTION

Roundup Ready Alfalfa varieties have in-plant tolerance to Roundup® agricultural herbicides, enabling farmers to apply labeled Roundup agricultural herbicides up to 5 days before cutting for unsurpassed weed control, excellent crop safety, and preservation of forage quality potential.

NOTE: The Pursuant to a Court Order issued on May 3, 2007, ROUNDUP READY ALFALFA SEED CAN NOT BE COMMERCIALLY SOLD OR PLANTED until further administrative regulatory actions are completed.

ROUNDUP AGRICULTURAL OVER-THE-TOP HERBICIDE PRODUCTS

Herbicide products sold by Monsanto for use over the top of Roundup Ready Alfalfa for the 2009 crop season are as follows:

- Roundup WeatherMAX
- Roundup PowerMAX®

For complete information about the use of Roundup agricultural herbicides over the top of Roundup Ready Alfalfa, refer to the appropriate Monsanto product's label booklet, or to supplemental labeling or fact sheets published separately by Monsanto. To learn more about applicable supplemental labels or fact sheets, call 1-800-ROUNDUP.

Tank-mixtures of Roundup agricultural herbicides with insecticides, fungicides, micronutrients or foliar fertilizers are not recommended as they may result in reduced weed control, crop injury, reduced pest control or antagonism. Refer to the Roundup agricultural herbicide product label, supplemental labeling, or fact sheets published separately by Monsanto for tank-mix recommendations.

You may use another glyphosate herbicide, but only if it has federally approved label instructions for use over Roundup Ready Alfalfa, and the product and the use label for Roundup Ready Alfalfa have been approved by your specific state. Contact the product manufacturers, the local retailers, or the local extension agents for confirmation that the products carry EPA and state approved labeling for this use. MONSANTO DOES NOT MAKE ANY REPRESENTATIONS, WARRANTIES OR RECOMMENDATIONS CONCERNING THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES THAT ARE LABELED FOR USE OVER ROUNDUP READY ALFALFA. MONSANTO SPECIFICALLY DENIES ALL RESPONSIBILITY AND DISCLAIMS ANY LIABILITY FOR ANY DAMAGE FROM THE USE OF THESE PRODUCTS IN ROUNDUP READY ALFALFA. ALL QUESTIONS AND COMPLAINTS CAUSED BY THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES SHOULD BE DIRECTED TO THE SUPPLIER OF THE PRODUCT IN QUESTION.

HAY AND FORAGE MANAGEMENT PRACTICES

Roundup Ready Alfalfa must be managed for high quality hay/forage production, including timely cutting to promote high forage quality (i.e. before 10% bloom) and to prevent seed development. In geographies where conventional alfalfa seed production is intermingled with forage production and the agronomic conditions (climate and water/irrigation availability) are such that forage alfalfa is allowed to stand and flower late in the season, Roundup Ready Alfalfa must be harvested at or before 10% bloom to minimize potential pollen flow from hay to common or conventional alfalfa seed production. Farmers who are unwilling to or who can not make this commitment to stewardship should not continue to grow Roundup Ready Alfalfa.

Roundup Ready Alfalfa varieties have excellent tolerance to over-the-top applications of labeled Roundup agricultural herbicides. An in-crop weed control program using Roundup WeatherMAX or Roundup PowerMAX will provide excellent weed control in most situations. A residual herbicide labeled for use in alfalfa may also be applied postemergence in alfalfa. Contact a Monsanto Representative, local crop advisor, or extension specialist to determine the best option for your situation.

Roundup Ready® Alfalfa

STAND TAKEOUT AND VOLUNTEER MANAGEMENT

Crop rotations can be divided into two main groups, alfalfa rotated to: 1) grass crops (e.g. corn and cereal crops); and 2) broadleaf crops. More herbicide alternatives exist for management of volunteer alfalfa in grass crops. The recommended steps for controlling volunteer Roundup Ready® Alfalfa are:

Diligent Stand Takeout

Use appropriate commercially available herbicide treatments alone for reduced tillage systems or in combination with tillage to terminate the Roundup Ready Alfalfa stand. Refer to your regional technical bulletin for specific stand takeout recommendations. NOTE: Roundup® agricultural herbicides are not effective for terminating Roundup Ready Alfalfa stands.

Start Clean

If necessary, utilize tillage and/or additional herbicide application(s) after stand takeout, and before planting of the subsequent rotational crop to manage any newly emerged or surviving alfalfa.

Plan for Success

Rotate to crops with known and available mechanical or herbicidal methods for managing volunteer alfalfa, keeping in mind that Roundup agricultural herbicides will not terminate Roundup Ready Alfalfa stands.

- Rotations to certain broadleaf crops are not advisable if the farmer is not willing to implement recommended stand termination practices.
- In the event that no known mechanical or herbicidal methods are available to manage volunteer alfalfa in the desired rotational crop, it is suggested that a crop with established volunteer alfalfa management practices be introduced into the rotation.

Timely Execution

Implement in-crop mechanical or herbicide treatments for managing alfalfa volunteers in a timely manner; that is, before the volunteers become too large to control or begin to compete with the rotational crop.

WEED RESISTANCE MANAGEMENT GUIDELINES

Follow the guidelines below to minimize the risk of developing glyphosate-resistant weed populations in a Roundup Ready Alfalfa system:

- Scout fields before and after each herbicide application.
- Use the right herbicide product at the right rate and at the right time.
- To control flushes of weeds in established alfalfa, make applications of Roundup WeatherMAX® or Roundup PowerMAX® herbicide at 22 to 44 oz/A before weeds exceed 6" in height, up to 5 days before cutting.
- Use other herbicide products tank-mixed or in sequence with Roundup agricultural herbicide if appropriate for the weed spectrum present as part of a Roundup Ready Alfalfa weed control program.
- Report repeated non-performance to Monsanto or your local retailer.

ROUNDUP READY ALFALFA STEWARDSHIP

All farmers shall sign the Monsanto Technology/ Stewardship Agreement (MTSA) limited-use license application which provides the terms and conditions for the authorized use of the product. Due to special circumstances, alfalfa farmers in the Imperial Valley of California will also sign an Imperial Valley Use Agreement (IVUA) with specific stewardship commitments.

Both the MTSA or IVUA explicitly prohibit all forms of commercial seed harvest on the stand. Every alfalfa farmer producing seed of Roundup Ready Alfalfa must possess an additional, separate, and distinct seed farmer contract to produce Roundup Ready Alfalfa seed.

Roundup Ready Alfalfa seed may not be planted outside of the United States, or for the production of seed or sprouts.

Any product produced from a Roundup Ready Alfalfa crop or seed, including hay and hay products, must be labeled and may only be used, exported to, processed, or sold in countries where regulatory approvals have been granted. It is a violation of national and international law to move material containing biotech traits across boundaries into nations where import is not permitted.

ROUNDUP READY ALFALFA STEWARDSHIP - *continued*

Pursuant to a Court Order issued on May 3, 2007, Roundup Ready Alfalfa farmers must adhere to the requirements set out in the December 13, 2007 USDA Administrative Order (**http://www.aphis.usda.gov/brs/pdf/RRA_A8_final.pdf**) until the USDA completes its regulatory process.

These requirements include, but are not limited to:

- Pollinators shall not be added to Roundup Ready Alfalfa fields grown only for hay production.
- Farm equipment used in Roundup Ready Alfalfa production shall be properly cleaned after use.
- Roundup Ready Alfalfa shall be handled and clearly identified to minimize commingling after harvest.

For additional information see the USDA website: **http://www.aphis.usda.gov/biotechnology alfalfa.shtml**

WEED CONTROL RECOMMENDATIONS

In established stands, to preserve the quality potential of forage and hay, applications should be made after weeds have emerged but before alfalfa re-growth interferes with application spray coverage of the target weeds.

PROGRAM	INSTRUCTIONS AND USE RATES	ADDITIONAL INFORMATION
Established Stands	After the first harvest of a newly established stand, up to 44 oz/A of Roundup WeatherMAX®* herbicide per cutting may be applied up to 5 days before each subsequent cutting. The combined total per year for all in-crop applications in established stands must not exceed 132 oz/A (4.1 qt/A) of Roundup WeatherMAX.	Applications between cuttings may be applied as a single application or in multiple applications (e.g. 2 applications of 22 oz/A). Sequential applications should be at least 7 days apart.
Weeds Controlled	For specific application rates and instructions for control of various annual and perennial weeds, refer to the Roundup WeatherMAX* herbicide label booklet. Some weeds with multiple germination times or suppressed (stunted) weeds may require a second application of Roundup WeatherMAX* herbicide for complete control. For some perennial weeds, repeated applications may be required to eliminate crop competition throughout the growing season.	In addition to those weeds listed in the Roundup WeatherMAX* label booklets, this product will suppress or control the parasitic weed, dodder (*Cuscuta spp.*) in Roundup Ready Alfalfa. Repeat applications may be necessary for complete control. For tough-to-control weeds or weeds not controlled by Roundup® agricultural herbicides use labeled rates of other herbicides, alone or in tank-mixtures, with Roundup agricultural herbicides.
Maximum Use Rates	**In-Crop:** • 44 oz/A per single application. • Established Stand Total: 44 oz/A per cutting up to 5 days before harvest.	**Total Per Year:** The combined total per year for all in-crop applications in established stands must not exceed 132 oz/A (4.1 qt/A) of Roundup WeatherMAX.

*If using another Roundup agricultural herbicide, you must refer to the label booklet or separately published Roundup Ready Alfalfa supplemental label for that brand to determine appropriate use rates. If using Roundup PowerMAX, application rates are the same as for Roundup WeatherMAX.

RECOMMENDATIONS FOR MANAGING GLYPHOSATE-RESISTANT WEEDS

In certain areas, populations of ryegrass, marestail, common ragweed, giant ragweed, *Palmer Amaranth* and waterhemp are known to be resistant to glyphosate. For control recommendations for resistant biotypes of these weeds, refer to **www.weedresistancemanagement.com** or call 1-800-ROUNDUP. When approved, supplemental labeling for specific herbicide products can also be viewed on **www.cdms.net** or **www.greenbook.net** or obtained by calling 1-800-ROUNDUP.

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Roundup Ready® Spring Canola

PRODUCT DESCRIPTION

Roundup Ready® Spring Canola varieties contain in-plant tolerance to Roundup agricultural herbicides, enabling farmers to apply Roundup® agricultural herbicides over the top of Roundup Ready Spring Canola anytime from emergence through the 6-leaf stage of development. The introduction of the Roundup Ready trait into leading spring canola hybrids and varieties gives farmers the opportunity for unsurpassed weed control, proven crop safety, and maximum profit potential. With Roundup Ready Spring Canola, farmers have the weed management tool necessary to improve spring canola profitability, while providing a viable rotational crop to help break pest and disease cycles in cereal-growing areas.

ROUNDUP AGRICULTURAL OVER-THE-TOP HERBICIDE PRODUCTS

Herbicide products sold by Monsanto for use over the top of Roundup Ready Spring Canola for the 2009 crop season are as follows:

- Roundup WeatherMAX®
- Roundup PowerMAX®

For complete information about the use of Roundup agricultural herbicides over the top of Roundup Ready Spring Canola, refer to the appropriate product's label booklet.

You may use another glyphosate herbicide, but only if it has federally approved label instructions for use over Roundup Ready Spring Canola, and the product and the use label for Roundup Ready Spring Canola have been approved by your specific state. Contact the product manufacturers, the local retailers, or the local extension agents for confirmation that the products carry EPA and state approved labeling for this use. MONSANTO DOES NOT MAKE ANY REPRESENTATIONS, WARRANTIES OR RECOMMENDATIONS CONCERNING THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES WHICH ARE LABELED FOR USE OVER ROUNDUP READY SPRING CANOLA. MONSANTO SPECIFICALLY DENIES ALL RESPONSIBILITY AND DISCLAIMS ANY LIABILITY FOR ANY DAMAGE FROM THE USE OF THESE PRODUCTS IN ROUNDUP READY SPRING CANOLA. ALL QUESTIONS AND COMPLAINTS CAUSED BY THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES SHOULD BE DIRECTED TO THE SUPPLIER OF THE PRODUCT IN QUESTION.

WEED RESISTANCE MANAGEMENT GUIDELINES

Follow the guidelines below to minimize the risk of developing glyphosate-resistant weed populations in a Roundup Ready Spring Canola System:

- Scout fields before and after each burndown and in-crop application.
- Start clean with a burndown herbicide or tillage.
- In-crop, apply RoundupWeatherMAX herbicide before weeds exceed 3" in height.
- A sequential application of Roundup WeatherMAX herbicide may be needed.
- Clean equipment before moving from field to field to minimize the spread of weed seed.
- Report repeated non-performance to Monsanto or your local retailer.

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Roundup Ready Spring Canola

WEED CONTROL RECOMMENDATIONS (SPRING-SEEDED)

PROGRAM	INSTRUCTIONS AND USE RATES	ADDITIONAL INFORMATION
Two-Pass Program–For Annual and Perennial Weed Control	For broad-spectrum control of annual and perennial weeds, use an initial application of 11 oz/A of Roundup WeatherMAX®*, in 5 to 10 gal/A water volume. No surfactant is required. Make a second application of 11 oz/A of Roundup WeatherMAX* no less than 10 days after initial application up to the 6-leaf stage (prebolting). Do not exceed 11 oz/A per application.	Spray when canola is at the 0- to 6-leaf stage of growth. To maximize yield potential, spray Roundup Ready Spring Canola at the 1- to 3-leaf stage to eliminate competing weeds. Short-term yellowing may occur with later applications, with little effect on crop growth, maturity, or yield. Wait a minimum of 10 days between applications. Two applications of Roundup WeatherMAX will: · Control late flushes of annual weeds such as foxtail, pigweed, and wild mustard. · Provide season-long suppression of Canada thistle, quackgrass, and perennial sow thistle. · Provide better yields by eliminating competition from both annuals and hard-to-control perennials.
Single Application–For Annual Weed Control	For broad-spectrum control of annual and easy-to-control perennial weeds, make a single application of 16 oz/A of Roundup WeatherMAX.*	For best results, spray Roundup Ready Spring Canola at the 2- to 3-leaf stage. Can be applied up to 6-leaf stage; yellowing may occur with later application with little effect on crop growth, maturity, or yield. No additional over-the-top applications can be made.
Maximum Use Rate For Roundup WeatherMAX	Two over-the-top applications: Do not exceed 11 oz/A per application. Single over-the-top applications: Do not exceed 16 oz/A. No additional application can be made.	

*If using another Roundup agricultural herbicide, you must refer to the label booklet or separately published Roundud Ready Alfalfa supplemental label for that brand to determine appropriate use rates if using RoundupPowerMAX, application rates are the same as for Roundup WeatherMAX.

PURCHASING AND PROTECTING ROUNDUP READY SPRING CANOLA TECHNOLOGY

Using Roundup Ready technology can improve weed control, increase profits, and help maximize your efficiency and productivity. Farmers must comply with the Canola Use Agreement (CUA) and the MTSA.

As with other Monsanto trait technologies, farmers must sign the MTSA before purchasing Roundup Ready Spring Canola. Farmers must then purchase a CUA to plant this patented technology. The CUA defines the number of Roundup Ready Spring Canola acres a farmer plans to grow and is available only through Monsanto Authorized Retailers. By signing the CUA, a farmer also agrees to meet certain conditions.

To purchase Roundup Ready Spring Canola, a farmer must follow these steps:

- **Sign the MTSA.**
  This agreement allows farmers to purchase all current and new Roundup Ready technologies. Farmers who sign agreements receive a Technology Card and Monsanto Technology I.D. number.
- **Sign up for Roundup Ready Spring Canola acres.**
  This requires farmers to purchase a CUA (as described in the previous section). Farmers may sign a "2-Application System CUA", a "Spring System CUA" or a "Non-Roundup Option CUA". The "2-Application System CUA" and "Spring System CUA" include Roundup WeatherMAX for use in Roundup Ready Spring Canola.
- **Purchase the seed.**
  To purchase Roundup Ready Spring Canola seed, farmers must provide a copy of their CUA to their seed dealer in order to receive seed.
- **Reconcile actual seeded acres.**
  A Monsanto Authorized Retailer will visit each farm and complete the legal description of the final planted acres on the CUA form. Monsanto randomly audits retailers for compliance with this reconciliation requirement through on-farm visits by a Canola Stewardship Representative.

Roundup Ready® Winter Canola

PRODUCT OESCRIPTION

Roundup Ready® Winter Canola varieties have been developed for seeding in the fall and harvesting the following spring/summer. Roundup Ready Winter Canola varieties contain in-plant tolerance to Roundup® agricultural herbicides, enabling farmers to apply Roundup agricultural herbicides over the top of Roundup Ready Winter Canola anytime from emergence to canopy closure or prior to bolting in the spring. The introduction of the Roundup Ready trait into winter canola varieties assures farmers of unsurpassed weed control, crop safety, and maximum yield potential. Roundup Ready Winter Canola offers farmers an important option as a rotational crop in traditional monoculture winter wheat production areas. Introducing crop rotation is an important factor in reducing pest cycles, including weed and disease problems.

ROUNOUP AGRICULTURAL OVER-THE-TOP HERBICIOE PRODUCTS

Herbicide products sold by Monsanto for use over the top of Roundup Ready Winter Canola for the 2009 crop season are as follows:

- Roundup WeatherMAX®
- Roundup PowerMAX®

You may use another glyphosate herbicide, but only if it has federally approved label instructions for use over Roundup Ready Winter Canola, and the product and the use label for Roundup Ready Winter Canola have been approved by your specific state. Contact the product manufacturers, the local retailers, or the local extension agents for confirmation that the products carry EPA and state approved labeling for this use. MONSANTO DOES NOT MAKE ANY REPRESENTATIONS, WARRANTIES OR RECOMMENDATIONS CONCERNING THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES WHICH ARE LABELED FOR USE OVER ROUNOUP READY WINTER CANOLA. MONSANTO SPECIFICALLY OENIES ALL RESPONSIBILITY AND DISCLAIMS ANY LIABILITY FOR ANY DAMAGE FROM THE USE OF THESE PRODUCTS IN ROUNDUP REAOY WINTER CANOLA. ALL QUESTIONS AND COMPLAINTS CAUSEO BY THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES SHOULD BE DIRECTEO TO THE SUPPLIER OF THE PRODUCT IN QUESTION. For complete information about the use of Roundup agricultural herbicide brands over the top of Roundup Ready Winter Canola, refer to the appropriate product's labeling.

WEED RESISTANCE MANAGEMENT GUIDELINES

Follow the guidelines below to minimize the risk of developing glyphosate-resistant weed populations in a Roundup Ready Winter Canola system:

- Scout fields before and after each burndown and in-crop application.
- Start clean with a burndown herbicide or tillage.
- In-crop, apply Roundup WeatherMAX herbicide at labeled rate before weeds exceed 3" in height.
- A sequential application of Roundup WeatherMAX herbicide at labeled rate may be needed.
- Clean equipment before moving from field to field to minimize the spread of weed seed..
- Report repeated non-performance to Monsanto or your local retailer.

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Roundup Ready Winter Canola

WEED CONTROL RECOMMENDATIONS (WINTER-SEEDED)

PROGRAM	INSTRUCTIONS AND USE RATES	ADDITIONAL INFORMATION
Sequential Applications	The two-pass program gives the greatest flexibility in controlling late emerging weeds. For broad-spectrum weed control, apply 11 to 22 oz/A of Roundup WeatherMAX* herbicide to 2-leaf or larger Roundup Ready Winter Canola in the fall. Use 5 to 10 gallons/A water volume. Do not add surfactants. Apply a second application of Roundup WeatherMAX* at 11 to 22 oz/A at a minimum interval of 60 days after the first application and before bolting in the spring. Do not exceed 22 oz/A per application.	Spray when Roundup Ready Winter Canola is at the 2-3 leaf stage of growth. Early applications can eliminate competing weeds and improve yield potential. Two applications of Roundup WeatherMAX will provide control of early emerging annual weeds and winter emerging weeds such as downy brome, cheat, and jointed goatgrass.
Single Application	For broad-spectrum control of annual and easy-to-control perennial weeds, make a single application of 16 to 22 oz/A of Roundup WeatherMAX*, preferably in the fall.	For best results, spray Roundup Ready Winter Canola at the 2-3 leaf stage and when weeds are small and actively growing. Applications must be made prior to bolting. Use the higher rate in the range when weed densities are high, when weeds have over-wintered or when weeds become large and well established.
Maximum Use Rate For Roundup WeatherMAX	Any single over-the-top application of Roundup WeatherMAX* should not exceed 22 oz/A. No more than two over-the-top applications may be made from crop emergence to canopy closure prior to bolting in the spring.	Applications of greater than 16 fluid ounces/A prior to the 6-leaf stage may result in temporary yellowing and/or growth reduction.

*If using another Roundup brand herbicide, you must refer to the label booklet or Roundup Ready Winter Canola supplemental label for that brand to determine appropriate use rates. If using Roundup PowerMAX, application rates are the same as for Roundup WeatherMAX.

GRAZING

It is recommended that Roundup Ready Winter Canola not be grazed. While Roundup Ready Winter Canola may provide farmers additional opportunity as a forage for grazing livestock, at the present time insufficient information exists to allow safe and proper grazing recommendations. Preliminary data suggest that excessive grazing can significantly reduce grain yield, and that careful nitrate management is critical in managing Roundup Ready Winter Canola as a forage to limit the risk of livestock nitrate poisoning. State universities are assessing the potential and the instructions for grazing Roundup Ready Winter Canola and they will provide grazing management guidelines when their research is completed.

RECOMMENDATIONS FOR MANAGING GLYPHOSATE-RESISTANT WEEDS IN ROUNDUP READY WINTER CANOLA

In certain areas, populations of ryegrass, marestail, common ragweed, giant ragweed, *Palmer Amaranth* and waterhemp are known to be resistant to glyphosate. For control recommendations for resistant biotypes of these weeds, refer to **www.weedresistancemanagement.com** or call 1-800-ROUNDUP. When approved, supplemental labeling for specific herbicide products can also be viewed on **www.cdms.net** or **www.greenbook.net.**

Roundup Ready® Sugarbeets

PRODUCT DESCRIPTION

Roundup Ready® Sugarbeet varieties have in-plant tolerance to Roundup® agricultural herbicides, enabling farmers to apply labeled Roundup agricultural herbicides from planting through 30 days prior to harvest for unsurpassed weed control, excellent crop safety, and preservation of yield potential.

ROUNDUP AGRICULTURAL OVER-THE-TOP HERBICIDE PRODUCTS

Herbicide products sold by Monsanto for use over the top of Roundup Ready Sugarbeets for the 2009 crop season are as follows:

- Roundup WeatherMAX®
- Roundup PowerMAX®

For complete information about the use of Roundup agricultural herbicides over the top of Roundup Ready Sugarbeets, refer to the appropriate Monsanto product label booklet, or to supplemental labeling or fact sheets published separately by Monsanto. To learn more about applicable supplemental labels or fact sheets, call 1-800-ROUNDUP.

Tank-mixtures of Roundup agricultural herbicides with insecticides, fungicides, micronutrients or foliar fertilizers are not recommended as they may result in reduced weed control, crop injury, reduced pest control or antagonism. Refer to the Roundup agricultural herbicide product label, supplemental labeling, or fact sheets published separately by Monsanto for tank-mix recommendations.

Sugarbeets are very sensitive to herbicide injury from phenoxy and other classes of herbicides. It is important to follow recommendations found on the herbicide product labels for cleaning spray tanks prior to adding Roundup agricultural herbicides to them.

You may use another glyphosate herbicide, but only if it has federally approved label instructions for use over Roundup Ready Sugarbeets, and the product and the use label for Roundup Ready Sugarbeets have been approved by your specific state. Contact the product manufacturers, the local retailers, or the local extension agents for confirmation that the products carry EPA and state approved labeling for this use. MONSANTO DOES NOT MAKE ANY REPRESENTATIONS, WARRANTIES OR RECOMMENDATIONS CONCERNING THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES THAT ARE LABELED FOR USE OVER ROUNDUP READY SUGARBEETS. MONSANTO SPECIFICALLY DENIES ALL RESPONSIBILITY AND DISCLAIMS ANY LIABILITY FOR ANY DAMAGE FROM THE USE OF THESE PRODUCTS IN ROUNDUP READY SUGARBEETS. ALL QUESTIONS AND COMPLAINTS CAUSED BY THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES SHOULD BE DIRECTED TO THE SUPPLIER OF THE PRODUCT IN QUESTION.

MANAGEMENT PRACTICES

Sugarbeets are extremely sensitive to weed competition for light, nutrients and soil moisture. Research on sugarbeet weed control suggests that sugarbeets need to be kept weed-free for the first eight weeks of growth to protect yield potential. Therefore, weeds must be controlled when they are small and before they compete with Roundup Ready Sugarbeets (exceed crop height), that is from less than 2" up to 4" in height, to preserve sugarbeet yield potential. *More than one in-crop herbicide application will be required* to control weed infestations to protect yield potential as Roundup agricultural herbicides have no soil residual activity. Bolting sugarbeets must be rogued or topped in Roundup Ready Sugarbeet fields.

Roundup Ready Sugarbeet varieties have excellent tolerance to over-the-top applications of labeled Roundup agricultural herbicides. A postemergence weed control program using Roundup WeatherMAX or Roundup PowerMAX will provide excellent weed control in most situations. A residual herbicide labeled for use in sugarbeet may also be applied preemergence, preplant, or postemergence in Roundup Ready Sugarbeets. Contact a Monsanto Representative, local crop advisor, or extension specialist to determine the best option for your situation.

Roundup Ready Sugarbeets

WEED RESISTANCE MANAGEMENT FOR ROUNDUP READY SUGARBEETS

Follow the guidelines below to minimize the risk of developing glyphosate-resistant weed populations in a Roundup Ready Sugarbeet system.

- Start clean with tillage and follow up with a burndown herbicide, such as Roundup agricultural herbicides, if needed prior to planting.
- Early season weed control is critical to protect sugarbeet yield potential. Apply the first in-crop application of Roundup WeatherMAX at a minimum of 22 oz/acre while weeds are less than 2" in height.
- Follow with additional postemergence in-crop application of Roundup WeatherMAX at a minimum of 22 oz/acre for additional weed flushes before weeds exceed 4" in height.
- Add spray grade ammonium sulfate at a rate of 17 lbs/100 gallons of spray solution with Roundup agricultural herbicides to maximize product performance.
- Use mechanical weed control/cultivation and/or residual herbicides where appropriate in your Roundup Ready Sugarbeets.
- Use additional herbicide modes of action/residual herbicides and/or mechanical weed control in other Roundup Ready crops you rotate with Roundup Ready Sugarbeets.
- Report repeated non-performance of Roundup agricultural herbicides to Monsanto or your local retailer.

AGRONOMIC PRINCIPLES IN SUGARBEETS

Sugarbeet yield is very sensitive to early-season weed competition. It is important to select the appropriate herbicide product, application rate and timing to minimize weed competition to protect yields. The Roundup Ready Sugarbeet system provides a mechanism to control weeds at planting and once Roundup Ready Sugarbeets emerge. Failure to control weeds with the right rate, at the right time, and with the right product, can lead to increased weed competition, weed escapes, and the potential for decreased yields. Tank-mixtures of Roundup agricultural herbicides with fungicides, insecticides, micronutrients or foliar fertilizers may result in crop injury and reduced pest control or antagonism and are not recommended.

In certain areas, populations of ryegrass, marestail, common ragweed, giant ragweed, *Palmer Amaranth*, waterhemp and johnsongrass are known to be resistant to glyphosate. For control recommendations for resistant biotypes of these weeds, refer to **www.weedresistancemanagement.com** or call 1-800-ROUNDUP. When approved, supplemental labeling for specific herbicide products can also be viewed on **www.cdms.net** or **www.greenbook.net** or obtained by calling 1-800-ROUNDUP.

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Roundup Ready® Sugarbeets

WEED CONTROL RECOMMENDATIONS

PROGRAM	INSTRUCTIONS AND USE RATES	ADDITIONAL INFORMATION
Preplant Burndown	After preplant tillage or bedding operations have been completed, a preplant burndown application of Roundup WeatherMAX®* at 22 to 44 oz/acre may be applied to control weeds that have germinated after tillage and prior to planting. See the label for appropriate rates by weed species and weed size.	Always utilize tillage to start with a weed-free field.
Over-The-Top Applications up to eight-leaf Roundup Ready Sugarbeets	Up to two applications of Roundup® agricultural herbicides may be made prior to the 8-leaf stage of Roundup Ready Sugarbeets. The first application of 22 to 32 oz/acre of Roundup WeatherMAX* should be made when weeds are less than 2" in height to protect yield potential. Make an additional application of 22 to 32 oz/acre of Roundup WeatherMAX before weeds exceed 4" in height. Maximum in-crop Roundup WeatherMAX prior to 8-leaf stage must not exceed 56 oz/acre.	Sugarbeets are sensitive to weed competition and can lose yield rapidly if weeds are not controlled early. More than one in-crop Roundup WeatherMAX application will be required to control weed infestations to protect yield potential as Roundup agricultural herbicides have no soil residual activity. Add ammonium sulfate at a rate of 17 lbs/100 gallons of spray solution with Roundup agricultural herbicides to maximize product performance. Tank-mixtures of Roundup agricultural herbicides with fungicides, insecticides, micronutrients or foliar fertilizers are not recommended. Sequential applications should be at least 7 days apart.
Over-The-Top Applications to greater than eight-leaf Roundup Ready Sugarbeets	Up to two additional applications of 22 oz/acre of Roundup WeatherMAX can be made after the eight-leaf stage up to 30 days prior to harvest. Maximum in-crop Roundup WeatherMAX from 8-leaf stage up until 30 days prior to harvest must not exceed 44 oz/acre.	Add ammonium sulfate at a rate of 17 lbs/100 gallons of spray solution with Roundup agricultural herbicides to maximize product performance. Tank-mixtures of Roundup agricultural herbicides with fungicides, insecticides, micronutrients or foliar fertilizers are not recommended. Sequential applications should be at least 7 days apart.
Maximum Use Rates	**In-Crop:** • Two applications of Roundup WeatherMAX prior to the 8-leaf stage of Roundup Ready Sugarbeets - 32 oz/acre per single application up to the 8-leaf stage. - Combined maximum of 56 oz/acre in-crop prior to the 8-leaf stage • Two applications of Roundup WeatherMAX after the 8-leaf stage up to 30 days prior to harvest - 22 oz/acre per single application after the 8-leaf stage. - Combined maximum of 44 oz/acre in-crop after the 8-leaf stage until 30 days prior to harvest	**Total Per Year:** The combined total per year for all Roundup WeatherMAX applications including pre-plant must not exceed 5.3 qt/acre. Total in-crop application must not exceed 3 qt/acre. Add ammonium sulfate at a rate of 17 lbs/100 gallons of spray solution with Roundup agricultural herbicides to maximize product performance. Tank-mixtures of Roundup agricultural herbicides with fungicides, insecticides, micronutrients or foliar fertilizers are not recommended.

*If using another Roundup agricultural herbicide, you must refer to the label booklet or separately published Roundup Ready Sugarbeets supplemental label for that brand to determine appropriate use rates. If using Roundup PowerMAX®, application rates are the same as for Roundup WeatherMAX.

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AUTHORIZED DEALERS AND RETAILERS

Authorized Dealers and Retailers are farmers' primary source of information on Roundup Ready®, YieldGard® and Bollgard® crops.

Any questions about Monsanto products should be directed to a seed company, Authorized Dealer/Retailer or Monsanto at 1-800-ROUNDUP.

Not all products are registered in all states and counties. Check the product registration status in your area.

For the most current listing of licensed patents, refer to the 2009 Monsanto Technology/Stewardship Agreement (MTSA).

Roundup Ready® Alfalfa seed may not be planted outside of the United States, or for the production of seed or sprouts. Any product produced from a Roundup Ready® Alfalfa crop or seed, including forage, hay and hay products, may only be used, exported to, processed or sold in countries where regulatory approvals have been granted. It is a violation of national and international law to move material containing biotech traits across boundaries into nations where import is not permitted. Roundup WeatherMAX® and Roundup PowerMAX® herbicides are approved in all states for use over-the-top with Roundup Ready® Alfalfa for forage and hay production.

Bullet®, Degree®, Degree Xtra®, Harness®, INTRRD®, Lariat®, and Micro-Tech® are restricted use pesticides and are not registered in all states. The distribution, sale or use of an unregistered pesticide is a violation of federal and/or state law and is strictly prohibited. Check with your local Monsanto dealer or Monsanto representative for the product registration status in your state.

Always Read and Follow Pesticide Label Directions. Roundup Ready® crops contain genes that confer tolerance to glyphosate, the active ingredient in Roundup® agricultural herbicides. Growers should be sure that the glyphosate product used over Roundup Ready® Flex cotton has been tested for that use so as to reduce the risk of leaf damage. See the Roundup Ready® Flex Technical Use Guide for details. Roundup® agricultural herbicides will kill crops that are not tolerant to glyphosate. Bollgard®, Bollgard® and design, Bollgard II®, Bollgard II® and design, Bullet®, Degree®, Degree Xtra®, Harness®, INTRRD®, Lariat®, Micro-Tech®, Respect the Refuge®, Respect the Refuge and design®, Roundup®, Roundud PowerMAX®, Roundup Ready®, Roundup Ready RAFE™, Roundup Technology®, Roundup WeatherMAX®, START CLEAN, STAY CLEAN.™, Transorb®, YieldGard®, YieldGard® Roorwerm, YieldGard® Rootworm with Roundup Ready® Corn2, YieldGard VT and Design®, YieldGard VT Rootworm/RR2®, YieldGard VT triple®, and Monsanto imagine® and the vine symbol are trademarks of Monsanto Technology LLC. Select Max® with Inside Technology™ are trademarks of Valent U.S.A. Corporation. All other trademarks are the property of their respective owners. ©2008 Monsanto Company. [18228Apgd] SA-9Y-08-304D

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Decision #: 398530
DP #: (359376)
NON PRIA
Parent DP #:
Submission #: 833609

DATA PACKAGE BEAN SHEET

Date: 09-Dec-2008

* * * Registration Information * * *

Registration: 524-575 - MON 89034

Company: 524 - MONSANTO COMPANY

Risk Manager: RM 92 - Dennis Szuhay - (703) 305-6098 Room# PY1 S-876

Risk Manager Reviewer: Jeannine Kausch JKAUSCH

Sent Date: 01-Aug-2008 Calculated Due Date: 17-Nov-2008 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (570) CONDITIONAL REGISTRATION FOLLOW-UP;DATA REQUIRED;REQUIRES RD REVI

Ingredients: 006515, Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-

006514, Bacillus thuringiensis CrylA.105 protein and genetic material necessary (vector PV-ZMIR245) for its production ir

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 04-Dec-2008 Due Back:

DP Ingredient: 006514, Bacillus thuringiensis CrylA.105 protein and genetic material necessary (vector PV-ZM

006515, Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-

DP Title: Response to Reg. Conditions - Tech Agreement

CSF Included: ◯ Yes ● No Label Included: ◯ Yes ● No Parent DP #:

Assigned To		Date In	Date Out	
Organization:	BPPD / MPB	04-Dec-2008		Last Possible Science Due Date: 21-May-2008
Team Name:	MPB IRM Science Review	04-Dec-2008		Science Due Date:
Reviewer Name:	Borges, Shannon	04-Dec-2008		Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Hi Shannon,

Per the registration notice for MON 89034, Monsanto has been asked to submit a copy of their grower agreement. Please review the language of this modified grower agreement to ensure that it is acceptable to the IRM team.

Thanks,

Jeannine

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July 29, 2008

Dr. Sheryl Reilly, Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
United States Environmental Protection Agency
Washington, DC 20460

Subject: Response to Conditions of Registration for MON 89034 (EPA Reg No. 524-575) and MON 89034 x MON 88017 (EPA Reg No. 524-576)

Dear Dr. Reilly:

On June 10, 2008, Monsanto received conditional registration approvals for MON 89034, EPA Reg. No. 524-575, and MON 89034 x MON 88017, EPA Reg. No. 524-576. Monsanto intends to comply with the conditions as outlined in the registration documents. However, in some cases Monsanto already has completed the requirements and submitted reports to EPA in the amendment request dated June 11, 2008 (more details below). The current submission is to address the following three requirements, and we will write to you with respect to other conditions and requirements in the future.

1. **On page 2 of the registration documents:** under **Insect Resistance Management, on cross resistance likelihood between Cry1A.105, Cry1Ac, Cry1F, EPA requested a study protocol, due August 1, 2008 and a final report, due April 1, 2009.**

Monsanto requests a waiver on submission of a study protocol prior to study initiation because the study has been completed. We had started the study prior to the registration based on the information we received from EPA in a letter dated December 19, 2007. Monsanto has completed the study and the report (MRID 474748-01: Head, G. P. 2008. Assessment of the impact of MON 89034 introduction on Bt resistance development in European and Southwestern corn borer.) was submitted to EPA in June 2008 to support the "Application to Amend the Registration of MON 89034".

In addition, there was a meeting between Monsanto and EPA on January 10, 2008. At the meeting, Monsanto proposed not to include Cry1Ac in the cross-resistance study given the similarity between Cry1Ac and Cry1Ab and the abundance of available information. It was agreed that Monsanto would provide a written rationale/literature review to explain why there is no need to include

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Cry1Ac in the cross resistance study and to include the rationale/literature review in the study report, which was also addressed (MRID 474748-01).

2 **On page 2 of the registration documents, under Insect Resistance Management, on simulation modeling in cotton growing areas, EPA requested a study protocol due, August 1, 2008 and a final report, due April 1, 2009.**

Monsanto requests a waiver of this additional modeling because our previous studies and the new information from the above cross-resistance study (MRID 474748-01) have adequately addressed the question of how cross-resistance may impact the durability of MON 89034. Additional simulation modeling including Cry1F adds no additional new information to understanding the nature of cross resistance in the cotton growing areas.

The modeling of resistance evolution in corn earworm (CEW) in southern cotton-growing states presented in the Head report of 2006 (MRID 469514-30, Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn, MON 89034) adequately captures the extreme case scenarios that exist for MON 89034 durability. That modeling was based on the model developed by Gustafson and Head (MRID 467172-02, Gustafson, D.I, and Head, G.P. 2005, Modeling the Impact of Natural Refuge on the Evolution of Tobacco Budworm and Cotton Bollworm Resistance to Bollgard II® Cotton.) with the following conservative assumptions:

(1) MON 89034 was assumed to be fully cross-resistant with Bollgard II cotton. That is, the Cry1A.105 protein in MON 89034 was assumed fully cross-resistant with the Cry1Ac in Bollgard II, and the Cry2Ab in both products was assumed fully cross-resistant.
(2) All cotton planted was assumed to be Bollgard II cotton, with no non-Bt cotton in the system.
(3) 80% of the corn planted in the region was assumed to be MON 89034, with 20% non-Bt corn.
(4) The modeling used cropping patterns from the Mississippi region because of the relatively higher risk of CEW resistance evolution in this region (Gustafson and Head, 2005).
(5) Resistance to the different Bt proteins was assumed to be complete, with no fitness costs.

These assumptions represent a clearly unrealistic worst-case scenario with respect to cross-resistance between Cry1Ac and Cry1A.105, Bollgard II and MON 89034 adoption in the region, and the resistance genetics. Even under these assumptions, the modeling results indicated that planting a 20% structured non-Bt corn refuge with MON 89034 was more than sufficient to manage the risk of resistance evolution to Bt corn and Bt cotton products; resistance evolved first to the Cry2Ab2 protein and took more than 24 years to arise.

Including Bt corn with Cry1F in the modeling (and including cross-resistance between Cry1F and Cry1A.105) will only slow the rate of resistance evolution because it would be replacing MON 89034 in the model. This would result in less selection for both Cry2Ab and Cry1A.105 resistance because:

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(a) Cry1F corn is associated with a 50% non-Bt corn refuge so replacing MON 89034 with Cry1F corn would increase the amount of non-Bt corn in the landscape.

(b) Cry1F has minimal or no efficacy against CEW [W. J. Moar, Auburn University, unpublished data; and Karim, S., Riazuddin, S., Gould, F., and Dean, D. H. 2000. Determination of receptor binding properties of *Bacillus thuringiensis* delta-endotoxins to cotton bollworm (*Helicoverpa zea*) and pink bollworm (*Pectinophora gossypiella*) midgut brush border membrane vesicles. Pesticide Biochemistry and Physiology 67: 198-216], and consequently the presence of Cry1F will not significantly select for Cry1F or Cry1A.105 resistance in CEW. If anything, Cry1F-containing products will act as partial refuge for MON 89034.

(c) The studies of Cry1F-resistant FAW and ECB described in Head report of 2008 (MRID 474748-01) indicate that cross-resistance between Cry1F and Cry1A.105 is typically low or insignificant.

In conclusion, the original modeling of MON 89034 durability in Head (2006) captures a more extreme worst-case than could modeling that includes Cry1F corn in the landscape, even if the Cry1F were assumed fully cross-resistant to Cry1A.105.

3. **On pages 3-5 of the registration documents, with respect to grower agreements and stewardship documents (points iii and v), EPA requests to submit a description by August 1, 2008**

Monsanto has modified the existing Technology/Stewardship Agreement (i.e., grower agreement) to include MON 89034 (trade name: YieldGard VT PRO™ corn) and MON 89034 x MON 88017 (trade name: YieldGard VT Triple PRO™ corn), in which growers are required to comply with IRM requirements. Specific IRM requirements for each product are specified in the Monsanto Technology Use Guide or TUG which is referenced in the grower agreement. A copy of the 2009 Monsanto Technology/Stewardship Agreement is attached herein.

If you have any questions regarding this letter please feel free to contact Dr. Russell Schneider, Senior Director, Monsanto Regulatory Affairs and Policy at (202) 383-2866, or me at (314) 694-2943 or yong.gao@monsanto.com.

Sincerely,

Yong Gao, Ph.D.
Regulatory Affairs Manager

Attachment: grower agreement on pages 4 and 5

cc: Russell Schneider, Monsanto
Carolyn Carrera, Monsanto

2009 MONSANTO TECHNOLOGY/STEWARDSHIP AGREEMENT

(Limited Use License)

PLEASE MAIL THE SIGNED 2009 MONSANTO TECHNOLOGY/STEWARDSHIP AGREEMENT TO:
Grower Licensing, Monsanto, 622 Emerson Road, Suite 150, St. Louis, MO 63141

GROWER INFORMATION (please print)

Please complete this section with your business information. To sign this Monsanto Technology/Stewardship Agreement ("Agreement") you must be the operator/Grower for all fields that will grow plants from Seed (as defined below). You represent that you have full authority to and do hereby bind to this Agreement yourself, all entities for which you obtain Seed, all individuals and entities having an ownership interest in any entities for which you obtain Seed, and that Monsanto Company has not barred any of those individuals or entities from obtaining this limited-use license. Your name must be filled in and must match the signature below. This Agreement becomes effective if and when Monsanto issues the Grower a license number from Monsanto's headquarters in St. Louis, Missouri. Monsanto does not authorize seed dealers or seed retailers to issue a license of any kind for Monsanto Technologies.

Grower's Full Legal Name (first/middle/last) Dr. Mr. Mrs. Ms. Suffix (Sr, Jr, II, III) **Farm Business Name**

Grower's Mailing Address **Farm Physical Address** (if different)

Grower's City **Farm City** **State** **Zip**

State **Zip** **Area Code** **Business Phone** **Fax** **Email**

SEED SUPPLIER

Business Name

Area Code **Phone** **City** **State** **Zip**

Form Number

THIS SPACE FOR MONSANTO OFFICE USE ONLY, PLEASE LEAVE THIS SECTION BLANK:

Lic. #: Batch #: Date:

This Monsanto Technology/Stewardship Agreement (s entered into between you (Grower) and Monsanto Company (Monsanto) and consists of the terms on this page and on the reverse side of this page.

This Monsanto Technology/Stewardship Agreement grants Grower a limited license to use Roundup Ready® soybeans, Roundup Ready 2 Yield™ soybeans, YieldGard® Corn Borer corn, YieldGard® Rootworm corn, YieldGard® Rootworm with Roundup Ready® Corn 2 corn, YieldGard® Plus corn, YieldGard® Plus with Roundup Ready® Corn 2 corn, Roundup Ready® Corn 2 corn, YieldGard® Corn Borer with Roundup Ready® Corn 2 corn, YieldGard VT Triple® corn, YieldGard VT Rootworm/RR2® corn, YieldGard VT PRO™ corn, YieldGard VT Triple PRO™ corn, YieldGard VT PRO/RR2™ corn, Roundup Ready® cotton, Bollgard® cotton, Bollgard® with Roundup Ready® cotton, Bollgard II® cotton, Bollgard II® with Roundup Ready® cotton, Roundup Ready® Flex cotton, Bollgard II® with Roundup Ready® Flex cotton, Maveta® High Value Corn with Lysine, Vistive® soybeans, Roundup Ready® sugar beets, Roundup Ready® canola, and Roundup Ready® alfalfa, ("Monsanto Technologies"). Seed containing Monsanto Technologies are referred to herein as ("Seed"). This Agreement also contains Grower's stewardship responsibilities and requirements associated with the use of Seed and Monsanto Technologies.

General Terms: Grower's rights may not be transferred to anyone else without the written consent of Monsanto. If Grower's rights are transferred with Monsanto's consent or by operation of law, this Agreement is binding on the person or entity receiving the transferred rights. If any provision of this Agreement is determined to be void or unenforceable, the remaining provisions shall remain in full force and effect. Grower acknowledges that Grower has received a copy of Monsanto's Technology Use Guide (TUG) and applicable Insect Resistance Management (IRM) Guide. To obtain additional copies of the TUG, contact Monsanto at 1-800-768-6387 or go to www.monsanto.com. Once effective, this Agreement will remain in effect until either the Grower or Monsanto choose to terminate the Agreement, as provided in Section 8 below. Information regarding new and existing Monsanto Technologies, including any additions or deletions to the U.S. patents licensed under this agreement, and any new terms will be mailed to you each year. Continuing use of Monsanto Technologies after receipt of any new terms constitutes Grower's agreement to be bound by the new terms.

GROWER RECEIVES FROM MONSANTO COMPANY:

- A limited use license to purchase and plant Seed and apply Roundup® agricultural herbicides and other authorized non-selective herbicides over the top of Roundup Ready® crops. Monsanto retains ownership of the Monsanto Technologies including the genes (for example, the Roundup Ready® gene) and the gene technologies. Grower receives the right to use the Monsanto Technologies subject to the conditions specified in this Agreement and for spring canola subject to the conditions in a separate use agreement.
- Monsanto Technologies are protected under U.S. patent law. Monsanto licenses the Grower, under applicable patents owned or licensed by Monsanto, to use Monsanto Technologies subject to the conditions listed in this Agreement. This license does not authorize Grower to plant Seed in the United States that has been purchased in another country or plant Seed in another country that has been purchased in the United States. Grower is not authorized to transfer Seed to anyone outside of the U.S.
- Enrollment for participation in Roundup Rewards® program.
- A limited use license to prepare and apply on glyphosate-tolerant soybean, cotton, alfalfa, or canola crops (or have others prepare and apply) tank mixes of, or sequentially apply (or have others sequentially apply), Roundup agricultural herbicides or other glyphosate herbicides labeled for use on those crops with quizalotop, clethodim, sethoxydim, fluazifop, and/or fenoxaprop to control volunteer Roundup Ready® Corn 2 corn in Grower's crops for the 2009 growing season. However, neither Grower nor a third party may utilize any type of co-pack or premix of glyphosate plus one or more of the above-identified active ingredients in the preparation of a tank mix.

PLEASE MAIL THE SIGNED 2009 MONSANTO TECHNOLOGY/STEWARDSHIP AGREEMENT TO: Grower Licensing, Monsanto, 622 Emerson Road, Suite 150, St. Louis, MO 63141.

UNITED STATES PATENTS: The licensed U.S. patents include: for Bollgard® cotton – 5,164,326; 5,196,525; 5,322,938; 5,352,605; 5,359,242; 5,530,196; 5,880,275; 6,943,282; for Bollgard II® cotton – 5,264,326; 5,196,525; 5,322,938; 5,338,544; 5,352,605; 5,359,142; 5,362,865; 5,530,196; 5,659,122; 5,727,084; 5,728,925; 5,880,275; 6,489,542; 6,943,282; 7,064,249; 7,223,907; for Bollgard II® with Roundup Ready® cotton – 5,264,326; 5,296,525; 5,322,938; 5,338,544; 5,352,605; 5,359,142; 5,362,865; 5,530,196; 5,659,222; 5,727,084; 5,728,925; 5,804,425; 5,880,275; 6,028,100; 6,051,753; 6,083,878; 6,489,542; 6,753,463; 6,943,282; 7,064,249; 7,223,907; RE39247; for Bollgard II® with Roundup Ready® Flex Cotton – 5,264,316; 5,196,525; 5,322,938; 5,338,544; 5,352,605; 5,359,142; 5,362,865; 5,530,196; 5,659,222; 5,717,084; 5,728,925; 5,804,425; 5,880,275; 6,052,753; 6,083,878; 6,489,542; 6,660,912; 6,753,463; 6,943,282; 6,949,696; 7,064,249; 7,222,725; 7,141,722; 7,223,907; RE39247; for Bollgard® with Roundup Ready® cotton – 5,164,326; 5,196,525; 5,322,938; 5,352,605; 5,359,142; 5,378,619; 5,530,196; 5,717,084; 5,728,925; 5,804,425; 5,880,275; 6,028,200; 6,052,753; 6,083,878; 6,753,463; 6,943,282; RE39247; for Bollgard® with Roundup Ready® Flex Cotton – 5,164,316; 5,196,525; 5,322,938; 5,352,605; 5,359,242; 5,530,196; 5,717,084; 5,728,925; 5,804,425; 5,880,275; 6,051,753; 6,083,878; 6,660,911; 6,753,463; 6,943,282; 6,949,696; 7,112,725; 7,241,722; RE39247; for Maveta® high value corn with lysine – 6,329,574; 7,157,281; for Roundup Ready 2 Yield™ Soybeans – 5,717,084; 5,728,925; 5,804,425; 6,052,753; 6,660,911; 6,949,696; 7,122,725; 7,241,722; RE39247; for Roundup Ready® Alfalfa –5,362,865; 5,378,619; 5,659,222; 5,727,084; 5,728,925; 5,804,425; 6,018,100; 6,051,753; RE39247; for Roundup Ready® Canola – 5,188,958; 5,378,629; 5,463,174; 5,463,175; 5,717,084; 5,728,925; 5,750,871; 5,804,425; 6,018,100; 6,052,753; 6,083,878; RE38825; RE39247; for Roundup Ready® Corn – 5,554,798; 5,641,876; 5,717,084; 5,728,925; 6,025,545; 6,040,497; 6,083,878; for Roundup Ready® Corn 2 – 5,264,316; 5,596,525; 5,322,938; 5,352,605; 5,359,142; 5,424,412; 5,554,798; 5,593,874; 5,642,876; 5,717,084; 5,728,925; 5,804,425; 5,859,347; 6,025,545; 6,083,878; 6,825,400; RE39247; for Roundup Ready® Cotton – 5,352,605; 5,378,619; 5,530,196; 5,717,084; 5,728,925; 5,804,425; 6,028,100; 6,052,753; 6,083,878; 6,753,463; RE39247; for Roundup Ready® Flex Cotton – 5,727,084; 5,728,925; 5,804,425; 6,052,753; 6,083,878; 6,660,922; 6,753,463; 6,949,696; 7,212,725; 7,141,722; RE39247; for Roundup Ready® Soybeans 5,352,605; 5,530,196; 5,727,084; 5,728,925; 5,804,425; RE39247; for Roundup Ready® Sugarbeets – 5,264,316; 5,196,525; 5,322,938; 5,352,605; 5,359,142; 5,378,619; 5,463,175; 5,530,196; 5,717,084; 5,728,925; 5,804,625; 6,028,100; 6,051,753; 6,083,878; 6,174,724; RE38825; RE39247; for YieldGard® Corn Borer corn – 5,352,605; 5,424,412; 5,484,954; 5,593,874; 5,859,347; 6,180,774; 6,331,665; 7,064,248; for YieldGard® Corn Borer with Roundup Ready® Corn – 5,264,316; 5,296,525; 5,322,938; 5,352,605; 5,359,242; 5,424,422; 5,484,956; 5,554,798; 5,593,874; 5,642,876; 5,717,084; 5,728,925; 5,804,425; 5,859,347; 6,025,545; 6,083,878; 6,331,665; 7,064,248; RE39247; for YieldGard® Corn Borer with Roundup Ready® Corn 2 – 5,264,326; 5,196,525; 5,322,938; 5,352,605; 5,359,242; 5,424,412; 5,484,956; 5,554,798; 5,593,874; 5,642,876; 5,727,084; 5,728,925; 5,804,425; 5,859,347; 6,025,545; 6,083,878; 6,180,774; 6,331,665; 6,825,400; 7,064,248; RE39247; for YieldGard® Corn Rootworm corn – 5,220,732; 5,352,605; 5,484,956; 6,063,597; 6,352,565; 6,501,009; 7,064,248; 7,227,056; for YieldGard® Plus corn – 5,220,732; 5,352,605; 5,424,422; 5,484,956; 5,593,874; 5,859,347; 6,063,597; 6,180,774; 6,331,665; 6,501,009; 7,064,248; 7,227,056; for YieldGard® Plus with Roundup Ready® Corn 2 – 5,210,732; 5,264,316; 5,296,525; 5,322,938; 5,352,605; 5,359,142; 5,424,422; 5,484,956; 5,554,798; 5,593,874; 5,642,876; 5,727,084; 5,728,925; 5,804,425; 5,859,347; 6,025,545; 6,063,597; 6,083,878; 6,180,774; 6,332,665; 6,501,009; 6,825,400; 7,064,248; 7,227,056; RE39247; for YieldGard® Rootworm with Roundup Ready® Corn 2 – 5,120,732; 5,264,316; 5,196,525; 5,322,938; 5,352,605; 5,359,142; 5,424,412; 5,484,956; 5,554,798; 5,642,876; 5,717,084; 5,728,925; 5,804,425; 5,859,367; 6,025,545; 6,063,597; 6,083,878; 6,331,665; 6,502,009; 6,825,400; 7,064,248; 7,227,056; RE39247; for YieldGard® VT Pro – 5,110,732; 5,164,316; 5,196,525; 5,322,938; 5,352,605; 5,359,242; 5,378,620; 5,424,412; 6,018,200; 6,051,753; 6,331,665; 6,489,542; 6,645,497; 6,962,705; 7,064,249; 7,250,501; for YieldGard® VT Pro/RR2 – 5,110,732; 5,164,316; 5,196,525; 5,322,938; 5,352,605; 5,359,142; 5,378,619; 5,424,422; 5,534,798; 5,593,874; 5,641,876; 5,717,084; 5,728,925; 5,804,425; 5,859,347; 6,018,100; 6,025,545; 6,051,753; 6,083,878; 6,332,665; 6,489,542; 6,825,400; 6,962,705; 7,064,249; 7,250,501; RE39247; for YieldGard® VT Rootworm/RR2 – 5,164,316; 5,196,525; 5,322,938; 5,352,605; 5,359,142; 5,554,798; 5,641,876; 5,717,084; 5,728,925; 5,804,425; 6,025,545; 6,063,597; 6,083,878; 6,332,665; 7,227,056; RE39247; for YieldGard® VT Triple – 5,164,326; 5,296,525; 5,322,938; 5,752,605; 5,353,542; 5,424,412; 5,484,956; 5,554,798; 5,593,874; 5,641,876; 5,717,084; 5,728,925; 5,804,425; 5,859,347; 6,025,545; 6,063,597; 6,083,878; 6,180,774; 6,332,665; 7,064,248; 7,227,056; RE39247; for YieldGard® VT Triple Pro – 5,110,732; 5,264,326; 5,296,525; 5,322,938; 5,352,605; 5,359,142; 5,378,619; 5,424,412; 5,554,798; 5,642,876; 5,717,084; 5,728,925; 5,804,625; 6,018,100; 6,025,545; 6,052,753; 6,063,597; 6,083,878; 6,332,665; 6,489,542; 6,645,497; 6,962,705; 7,064,249; 7,227,056; 7,850,501; RE39247; for tank mix - 6,239,072 .

ALWAYS READ AND FOLLOW PESTICIDE LABEL DIRECTIONS. Roundup Ready® crops contain genes that confer tolerance to glyphosate, the active ingredient in Roundup® agricultural herbicides. Roundup® agricultural herbicides will kill crops that are not tolerant to glyphosate. Bollgard®, Bollgard II®, Roundup®, Roundup Ready®, Roundup Ready 2 Yield™, Roundup Technology®, Roundup Rewards®, Vistive®, YieldGard®, YieldGard® Corn Borer and Design, YieldGard® Rootworm and Design, YieldGard® Plus and Design, YieldGard VT Triple®, YieldGard VT Rootworm/RR2®, YieldGard VT PRO™, YieldGard VT Triple PRO™, YieldGard VT PRO/RR2™, Grow the Feed, Not the Weeds.®, and Monsanto Imagine® and the Vine Design are trademarks of Monsanto Technology LLC. Maveta® is a registered trademark of Renessen LLC. ©2001-2009 Monsanto Company. [18362Cpgd] SB-9Y-08-3116

GROWER AGREES:

- To direct grain produced from crops containing trait starks (including but not limited to the Roundup Reapy® Corn 2 and/or YieldGard® Rootworm trait(s)) to appropriate markets as necessary.
- Only to lawfully plant Roundup Ready® alfalfa; and not to plant Roundup Ready® alfalfa for the production of sprouts, or of seed unless under specific contract to produce seed. If growing Roundup Ready® alfalfa, to direct any product produced from a Roundup Ready® alfalfa seed or crop, including hay and hay products, only to those countries where regulatory approvals have been granted, and to grow and manage Roundup Ready® alfalfa in accordance with the Technology Use Guide.
- To accept and continue the obligations of this Monsanto Technology/Stewardship Agreement on any new land purchased or leased by Grower that has Seed planted on it by a previous owner or possessor of the land; and to notify in writing purchasers or lessees of land owned by Grower that has Seed planted on it that the Monsanto Technology is subject to this Monsanto Technology/Stewardship Agreement and they must have or obtain their own Monsanto Technology/Stewardship Agreement.
- To implement an Insect Resistance Management (IRM) program as specified in the applicable Bollgard®/Bollgard II® cotton and YieldGard® corn sections of the most recent Technology Use Guide (TUG) and Insect Resistance Management (IRM) guides and to cooperate and comply with these Insect Resistance Management programs.
- To use Seed containing Monsanto Technologies solely for planting a single commercial crop.
- Not to save or clean any crop produced from Seed for planting and not to supply Seed produced from Seed to anyone for planting other than to a Monsanto licensed seed company.
- Not to transfer any Seed containing patented Monsanto Technologies to any other person or entity for planting.
- To plant and/or clean Seed for Seed production, if and only if, Grower has entered into a valid, written Seed production agreement with a Seed company that is licensed by Monsanto to produce Seed. Grower must either physically deliver to that licensed Seed Company or must sell for non-seed purposes or use for non-seed purposes all of the Seed produced pursuant to a Seed production agreement. Grower may NOT plant and may not transfer to others for planting any Seed for crop breeding, research, or generation of herbicide registration data.
- To use on Roundup Ready® crops only a labeled Roundup® agricultural herbicide or other authorized non-selective herbicide which could not be used in the absence of the Roundup Ready® gene (see TUG for details on authorized non-selective products). Use of any selective herbicide labeled for the same crop without the Roundup Ready® gene is not restricted by this Agreement. MONSANTO DOES NOT MAKE ANY REPRESENTATIONS, WARRANTIES OR RECOMMENDATIONS CONCERNING THE USE OF PRODUCTS MANUFACTURED OR MARKETED BY OTHER COMPANIES WHICH ARE LABELED FOR USE WITH ROUNDUP READY® CROP(S). MONSANTO SPECIFICALLY DISCLAIMS ALL RESPONSIBILITY FOR THE USE OF THESE PRODUCTS IN ROUNDUP READY® CROP(S). ALL QUESTIONS AND COMPLAINTS ARISING FROM THE USE OF PRODUCTS MANUFACTURED OR MARKETED BY OTHER COMPANIES SHOULD BE DIRECTED TO THOSE COMPANIES.
- To read and follow the applicable sections of the TUG, which is incorporated into and is a part of this Agreement, for specific requirements relating to the terms of this Agreement, and to abide by and be bound by the terms of the TUG as it may be amended from time to time.
- To acquire Seed containing these Monsanto Technologies only from a seed company with technology license(s) from Monsanto or from a licensed company's authorized dealer.
- To pay all applicable fees due to Monsanto that are a part of, associated with or collected with the Seed purchase price or that are invoiced for the seed. If Grower fails to pay Monsanto for cotton related Monsanto Technologies, Grower agrees to pay Monsanto default charges at the rate of 18% per annum (or the maximum allowed by law whichever is less) from September 1, 2009, plus Monsanto's reasonable attorney fees, court costs, and all other costs of collection.
- Upon written request to the Grower, to allow Monsanto to review the Farm Service Agency crop reporting information on any land farmed by Grower including Summary Acreage History Report, Form 578 and corresponding aerial photographs, Risk Management Agency claim documentation, and dealer/retailer invoices for seed and chemical transactions.
- To allow Monsanto to examine and copy any records and receipts that could be relevant to Grower's performance of this Agreement.

GROWER UNDERSTANDS:

- Commodity Marketing: Grain/commodities harvested from YieldGard® Rootworm corn, YieldGard® Plus corn, YieldGard® Plus with Roundup Ready® Corn 2 corn, YieldGard® Rootworm, YieldGard® Rootworm with Roundup Ready® Corn 2 corn, YieldGard® Corn Borer with Roundup Ready® Corn 2 corn, YieldGard VT Triple® corn, YieldGard VT Rootworm/RR2® corn and Roundup Ready® canola are approved for U.S. food and feed use but not yet approved in certain export markets where approval is not certain to be received before the end of 2009. As a result, Grower must direct those grain/commodities to the following approved market options: feeding on farm, use in domestic feed lots, elevators that agree to accept the grain, or other approved uses in domestic markets only. Go to www.866sellcorn.com for a list of Grain Handlers' positions on accepting transgenic corn. The American Seed Trade Association web site (www.amseed.org) includes a list of grain handlers' positions on accepting transgenic corn. You must complete and send to Monsanto a Market Choices® Grain Marketing Communication Plan, for additional information on grain market options or to obtain additional forms, call 1-800-768-6387.
- Growers must sell any product produced from a Roundup Ready 2 Yield™ soybean, YieldGard VT Triple® corn, YieldGard VT Rootworm/RR2® corn, Mavera® High Value Corn with Lysine seed to entities in those countries where full regulatory approvals for these products have been granted.
- Regulatory approvals: Monsanto Technologies may only be planted where the products have been approved for use by all required governmental agencies. For example, some Monsanto Technologies are not approved for planting in all states or all counties within a state. Check with your Monsanto representative if you have questions about the approval status in your state.
- Insect Resistance Management (IRM): When planting any YieldGard® or Bollgard® product, Grower must implement an IRM program according to the size and distance guidelines specified in the Bollgard® cotton and YieldGard® corn sections of the most recent Monsanto Technology Use Guide including any supplemental amendments (collectively "TUG") and the crop specific IRM guides. Grower may lose Grower's limited use license to use these products if Grower fails to follow the IRM program required by this Agreement.
- Crop Stewardship & Specialty Crops: Refer to the section on Coexistence and Identity Preservation in the TUG for information on crop stewardship and considerations for production of identity preserved crops.
- Corn Trait Performance: All hybrids containing Monsanto corn traits (YieldGard® Corn Borer corn, YieldGard® Rootworm corn, YieldGard® Plus corn, and Roundup Ready® Corn 2 corn) have been screened for the presence of the appropriate protein and have passed this screening prior to commercial sale. YieldGard® Rootworm corn and YieldGard® Plus corn hybrids have achieved industry leading success rates in excess of 99%. A small number of these hybrids may infrequently demonstrate variable levels of performance in fields and not meet Grower expectations.

TERMINATION: Grower or Monsanto may choose to terminate this Agreement effectively immediately by delivering written notice to either party. Grower must deliver the notice of termination to Grower Licensing, Monsanto, 622 Emerson Road, Suite 150, St. Louis, MO 63141. If this Agreement is terminated pursuant to such a notice, Grower's responsibilities and the other terms herein shall survive (such as but not limited to Grower's obligation to use Seed for a single commercial crop) as to Seed previously purchased by the Grower.

In the event Grower violates the terms of this Agreement, then this Agreement shall automatically terminate. However, Grower's responsibilities and the other terms herein shall survive as to all Seed purchased or used by the Grower prior to such violation (such as but not limited to Grower's obligation to use Seed for a single commercial crop, Grower's obligation to pay Monsanto for its attorneys' fees, costs and other expenses incurred in enforcing its rights under this Agreement, and Grower's agreement to the choice of law and forum selection provisions contained herein). Further, Grower shall not be entitled to obtain a future limited-use license from Monsanto unless Monsanto provides Grower with specific written notice expressly recognizing the prior breach and prior termination of the limited-use license and expressly granting and/or reissuing the limited-use license previously obtained (and terminated) pursuant to this Agreement. Grower expressly acknowledges that Grower's submission of a new Monsanto Technology Stewardship Agreement and Monsanto's issuance of a new license number shall not satisfy the specific written notice requirement above and that any such action shall have no legal effect. If Grower is found by any court to have breached any term of this Agreement and/or to have infringed one or more of the U.S. patents listed below, Grower agrees that, among other things, Monsanto will be entitled to preliminary and permanent injunctions enjoining Grower and any individual and/or entity acting on Grower's behalf or in concert therewith from making, using, selling, or offering Seed for sale. Additionally, Grower agrees that any such finding of infringement by Grower shall entitle Monsanto to patent infringement damages to the full extent authorized by 35 U.S.C. § 271 et. seq. Grower will also be liable for all breach of contract damages. If Grower is found by any court to have infringed one or more of the U.S. patents listed below or otherwise to have breached this Agreement, Grower agrees to pay Monsanto and the licensed Monsanto Technology provider(s) their attorneys' fees and costs and other expenses incurred in enforcing rights under this Agreement including, but not limited to, expenses incurred in the investigation of the breach of this Agreement and/or infringement of one or more of the U.S. patents listed below.

Grower accepts the terms of the following NOTICE REQUIREMENT, LIMITED WARRANTY AND DISCLAIMER OF WARRANTY AND EXCLUSIVE LIMITED REMEDY by signing this Agreement and/or opening a bag of Seed. If Grower does not agree to be bound by the conditions of purchase or use, Grower agrees to return the unopened bags to Grower's seed dealer.

NOTICE REQUIREMENT: As a condition precedent to Grower or any other person with an interest in Grower's crop asserting any claim, action, or dispute against Monsanto and/or any seller of Seed regarding performance or non-performance of Monsanto Technologies or Seed, Grower must provide Monsanto a written, prompt, and timely notice (regarding performance or non-performance of the Monsanto Technologies) and to the seller of any Seed (regarding performance or non-performance of the Seed) within sufficient time to allow an in-field inspection of the crop(s) about which any controversy, claim, action, or dispute is being asserted. The notice will be timely only if it is delivered 15 days or less after the Grower first observes the issue(s) regarding performance or non-performance of the Monsanto Technology and/or the Seed. The notice shall include a statement setting forth the nature of the claim, name of the Monsanto Technology, and Seed hybrid or variety. Grower must deliver the notice to Grower Licensing, Monsanto, 622 Emerson Road, Suite 150, St. Louis, MO 63141.

LIMITED WARRANTY AND DISCLAIMER OF WARRANTIES: Monsanto warrants that the Monsanto Technologies licensed hereunder will perform as set forth in the TUG when used in accordance with directions. This warranty applies only to Monsanto Technologies contained in planting Seed that has been purchased from Monsanto and seed companies licensed by Monsanto or the seed companies' authorized dealers or distributors. EXCEPT FOR THE EXPRESS WARRANTIES IN THE LIMITED WARRANTY SET FORTH ABOVE, MONSANTO MAKES NO OTHER WARRANTIES OF ANY KIND, AND DISCLAIMS ALL OTHER WARRANTIES, WHETHER ORAL OR WRITTEN, EXPRESS OR IMPLIED INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PARTICULAR PURPOSE.

GROWER'S EXCLUSIVE LIMITED REMEDY: THE EXCLUSIVE REMEDY OF THE GROWER AND THE LIMIT OF THE LIABILITY OF MONSANTO OR ANY SELLER FOR ANY AND ALL LOSSES, INJURY OR DAMAGES RESULTING FROM THE USE OR HANDLING OF SEED (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, PRODUCT LIABILITY, STRICT LIABILITY, TORT, OR OTHERWISE) SHALL BE THE PRICE PAID BY THE GROWER FOR THE QUANTITY OF THE SEED INVOLVED OR, AT THE ELECTION OF MONSANTO OR THE SEED SELLER, THE REPLACEMENT OF THE SEED. IN NO EVENT SHALL MONSANTO OR ANY SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL, OR PUNITIVE DAMAGES.

Thank you for choosing our advanced technologies. We look forward to working with you in the future. If you have any questions regarding the Monsanto Technologies or this license, please call the Monsanto Customer Relations Center at: 1-800-768-6387.

GOVERNING LAW: This Agreement and the parties' relationship shall be governed by the laws of the State of Missouri and the United States (without regard to the choice of law rules).

BINDING ARBITRATION FOR COTTON-RELATED CLAIMS MADE BY GROWER: Any claim or action made or asserted by a cotton Grower (or any other person claiming an interest in the Grower's cotton crop) against Monsanto or any seller of cotton Seed containing Monsanto Technology arising out of and/or in connection with this Agreement or the sale or performance of the cotton Seed containing Monsanto Technology other than claims arising under the patent laws of the United States must be resolved by binding arbitration. The parties acknowledge that the transaction involves interstate commerce. The parties agree that arbitration shall be conducted pursuant to the provisions of the Federal Arbitration Act, 9 U.S.C. Sec. 1 et seq. and administered under the Commercial Dispute Resolution Procedures established by the American Arbitration Association ("AAA"). The term "seller" as used throughout this Agreement refers to all parties involved in the production, development, distribution, and/or sale of the Seed containing Monsanto Technology. In the event that a claim is not amicably resolved within 30 days of Monsanto's receipt of the Grower's notice required pursuant to this Agreement any party may initiate arbitration. The arbitration shall be heard in the capital city of the state of Grower's residence or in any other place as the parties decide by mutual agreement. When a demand for arbitration is filed by a party, the Grower and Monsanto/sellers shall each immediately pay one half of the AAA filing fee. In addition, Grower and Monsanto/sellers shall each pay one half of AAA's administrative and arbitrator fees as those fees are incurred. The arbitrator(s) shall have the power to apportion the ultimate responsibility for all AAA fees in the final award. The arbitration proceedings and results are to remain confidential and are not to be disclosed without the written agreement of all parties, except to the extent necessary to effectuate the decision or award of the arbitrator(s) or as otherwise required by law.

FORUM SELECTION FOR NON-COTTON-RELATED CLAIMS MADE BY GROWER AND ALL OTHER CLAIMS: THE PARTIES CONSENT TO THE SOLE AND EXCLUSIVE JURISDICTION AND VENUE OF THE U.S. DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, EASTERN DIVISION, AND THE CIRCUIT COURT OF THE COUNTY OF ST. LOUIS, MISSOURI, (ANY LAWSUIT MUST BE FILED IN ST. LOUIS, MO) FOR ALL CLAIMS AND DISPUTES ARISING OUT OF OR CONNECTED IN ANY WAY WITH THIS AGREEMENT AND/OR THE USE OF THE SEED OR THE MONSANTO TECHNOLOGIES, EXCEPT FOR COTTON-RELATED CLAIMS MADE BY GROWER. THE PARTIES WAIVE ANY OBJECTION TO VENUE IN THE EASTERN DIVISION OF THE U.S. DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, INCLUDING THOSE BASED, IN WHOLE OR IN PART, ON THE DIVISIONAL VENUE LOCAL RULE(S) OF THE U.S. DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI.

THIS AGREEMENT CONTAINS A BINDING ARBITRATION PROVISION FOR COTTON RELATED CLAIMS PURSUANT TO THE PROVISIONS OF THE FEDERAL ARBITRATION ACT, 9 U.S.C. § ET SEQ., WHICH MAY BE ENFORCED BY THE PARTIES.

GROWER SIGNATURE & DATE REQUIRED

Name Monsanto Company

Date

(161)

DATA PACKAGE BEAN SHEET

Date: 09-Dec-2008

Decision #: 394798
DP #: (359500)
PRIA
Parent DP #:
Submission #: 832528

* * * Registration Information * * *

Registration: 524-575 - MON 89034

Company: 524 - MONSANTO COMPANY

Risk Manager: RM 92 - Dennis Szuhay - (703) 305-6098 Room# PY1 S-8761

Risk Manager Reviewer: Jeannine Kausch JKAUSCH

Sent Date: 15-Jul-2008 Calculated Due Date: 29-Dec-2008 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (B900) AMENDMENT;PIP;NON-FAST-TRACK (EXCEPT B89 ABOVE);

Ingredients: 006515, Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-

006514, Bacillus thuringiensis Cry1A.105 protein and genetic material necessary (vector PV-ZMIR245) for its production i

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 17-Jul-2008 Due Back:

DP Ingredient: 006514, Bacillus thuringiensis Cry1A.105 protein and genetic material necessary (vector PV-ZM

006515, Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-

DP Title:

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #:

Assigned To		Date In	Date Out	
Organization:	BPPD / MPB	17-Jul-2008	12-Nov-2008	Last Possible Science Due Date: 02-Jul-2008
Team Name:	MPB IRM Science Review	17-Jul-2008	12-Nov-2008	Science Due Date:
Reviewer Name:	Reynolds, Alan	17-Jul-2008	12-Nov-2008	Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

MRID #474748-01 "Assessment of the Impact of MON 89034 Introduction to Bt Resistance Development in European and Southwestern Corn Borer"

Hi Alan,

Please find attached the IRM study for MON 89034 and MON 89034 x MON 88017. I've also sent an electronic copy via email. The Phase IV date is November 14, 2008. Let me know if you have any questions or if you need to renegotiate the completion date.

Thanks!

Jeannine

(162)

DP#: (359500) *** Studies Sent for Review *** Decision#: (394798)

MRID	MRID Status	Citation Reference	Guideline
47474801	Acceptable	Head, G. (2008) Assessment of the Impact of MON 89034 Introduction on Bt Resistance Development in European and Southwestern Corn Borer. Project Number: MSL0021297. Unpublished study prepared by Monsanto Company. 35 p.	

Memorandum

Date: 02/15/08

To: PM 92, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

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UN.. ED STATES ENVIRONMENTAL PROTEC ON AGENCY
WASHINGTON, D.C. 20460

July 15, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

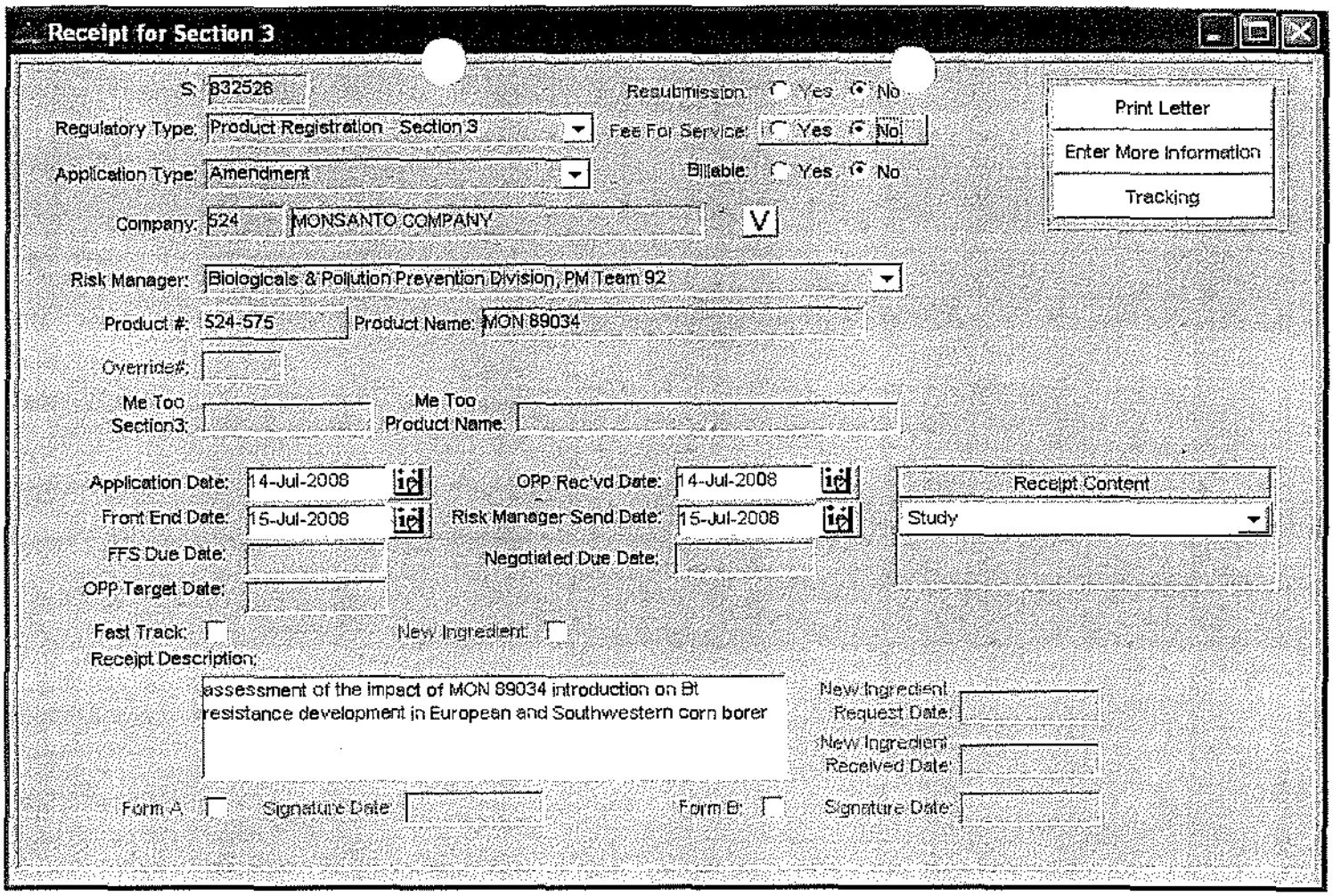
MONSANTO COMPANY
1300 I STREET, NW, SUITE 450 EAST
WASHINGTON, DC 20005

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 14-JUL-08. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

165


Receipt for Section 3
S: 832526
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Company: 524 MONSANTO COMPANY
Print Letter
Enter More Information
Tracking
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 92
Product #: 524-575
Product Name: MON 89034
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 14-Jul-2008
OPP Rec'vd Date: 14-Jul-2008
Receipt Content
Front End Date: 15-Jul-2008
Risk Manager Send Date: 15-Jul-2008
Study
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Fast Track:
New Ingredient:
Receipt Description:
assessment of the impact of MON 89034 introduction on Bt resistance development in European and Southwestern corn borer
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

MONSANTO
imagine

MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST LOUIS, MISSOURI 63167
http://www.monsanto.com

June 11, 2008

Dr. Sheryl Reilly, Chief
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: Application to amend the registration of MON 89034 x MON 88017, EPA Registration No. 524-576 + 524-575

Dear Dr. Reilly:

On June 10, 2008, EPA granted Monsanto Company a conditional registration (EPA Reg No. 524-576) for corn MON 89034 x MON 88017 insect protection and herbicide tolerance corn with an expiration date of September 30, 2010. The registration requires that growers set aside 20% of their corn acres as a structured refuge for corn borers. Monsanto herein requests to amend the registration of MON 89034 x MON 88017 to allow for 5% structured refuge in the Corn Belt (non-cotton growing regions) for corn borers.

MON 89034 x MON 88017 was developed by conventional breeding of corn plants of event MON 89034 and MON 88017. MON 89034 x MON 88017 produces two lepidopteran active Bt proteins, Cry1A.105 and Cry2Ab2, and a corn rootworm active Bt Cry3Bb1 protein. The two lepidopteran active proteins have important differences in their modes of action, which were discussed in the original registration request (Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn MON 89034. MRID 469514-30. Head, G. 2006. Insect Resistance Management Plan for the Combined Trait Product MON 89034 x MON 88017. MRID 469513-06). In view of the dual effective dose and the distinct mode of action of the two proteins, the likelihood of resistance evolution is significantly reduced compared to single Bt protein

(167)

products. Therefore, MON 89034 x MON 88017 is expected to be sustainable using a reduced structured refuge with respect to corn borers. In the petition to EPA for registration filed in September 2006, Monsanto requested to reduce structured refuge for corn borers in the U.S. Corn Belt to 5% for MON 89034 x MON 88017 compared to the 20% for existing single lepidopteran-active Bt protein-containing corn products. Monsanto also requested to reduce structured refuge for corn borers in the southern cotton-growing regions to 20% for MON 89034 x MON 88017 compared to 50% for single lepidopteran-active Bt protein-containing corn products.

EPA granted a 20% structured refuge requirement for MON 89034 x MON 88017 in the southern cotton-growing regions in the registration, EPA Reg No. 524-576. In a letter to Monsanto dated December 19, 2007, EPA indicated that they would require additional data to support MON 89034 field corn uses in the Corn Belt with a 5% structured refuge, specifically data on dose determination, cross resistance potential among Cry1A.105, Cry1F and Cry1Ac, and additional simulation modeling. Monsanto has generated additional data which consistently support the conclusion of the original petition submitted to EPA in September 2006. The additional data and assessment showed that under all adoption, cross-resistance, and efficacy scenarios, deployment of MON 89034 with a refuge size of 5% was more durable than single trait products with 20% refuge and, in the more realistic scenarios, the pyramid was many times more effective than the single Bt products in delaying resistance in both European corn borer (ECB) and Southwestern corn borer (SWCB). The additional data were included in the "Application to Amend the Registration of MON 89034, EPA Registration No. 524-575", submitted by Monsanto Company.

In support of this application for an amendment, Monsanto is submitting the following:

- Transmittal Document

- Volume 1 of 1: Gao, Y. 2008. Administrative materials for the application to amend the registration of the plant-incorporated protectant *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, and Cry3Bb1 proteins and the genetic material (vectors PV-ZMIR245 and PV-ZMIR39) necessary for their production in MON 89034 x MON 88017. This volume includes the following:
    1. Application for Pesticide Amendment (EPA Form 8570-1)*
    2. Certification with Respect to Citation of Data (EPA Form 8570-34)*
    3. Data Matrix (EPA Form 8570-35)**
    4. Product Label*
    5. Confidential Statement of Formula (CSF)***

    Note on confidentiality classification:
    - * Category A: Non-confidential and can be released to public
    - ** Category B: Subject to the provisions of FIFRA Section 10(g) and therefore protected from disclosure to multinational or foreign pesticide producers. Redacted data matrix is non-confidential and can be released to public.
    - *** Category C: Confidential business information that is protected from any disclosure indefinitely by provision of FIFRA Section 10.

47474801 • Vol. 2 Assessment of the Impact of MON 89034 Introduction on Bt Resistance Development in European + Southwestern Corn Borer

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On June 2, 2005 the Federal Register published a notice from the EPA regarding fees and decision times for pesticides registrations [FR 70(105): 32327-32335]. Based on the "Pesticide Registration Improvement Renewal Act – PRIA II Fee Table – Effective October 1, 2007" published by EPA, this proposed amendment request to the registration of MON 89034 x MON 88017 belongs to category B900 – Amendment (e.g., new IRM requirements that are applicant initiated; or amending a conditional registration to extend the registration expiration date with additional data submitted). The fee for category B900 is $10,500. Monsanto will wire this amount to EPA through electronic transfer.

If you have any questions with respect to this amendment request, please feel free to contact Dr. Russell Schneider, Senior Director, Monsanto Regulatory Affairs and Policy at (202) 383-2866, or me at the phone number or e-mail listed below. Thank you for your attention.

Sincerely,

Yong Gao, Ph.D.
Regulatory Affairs Manager
(314) 694-2943 (office)
yong.gao@monsanto.com

cc: Russell Schneider, Monsanto
Carolyn Carrera, Monsanto

"GAO, YONG [AG/1000]"
<yong.gao@monsanto.com>
07/11/2008 04:36 PM

To Jeannine Kausch/DC/USEPA/US@EPA
cc "SCHNEIDER, RUSSELL P [AG/1920]"
<russell.p.schneider@monsanto.com>
bcc
Subject RE: EPA Reg. Nos. 524-575 and 524-576 - Request for electronic courtesy copy of study

History: This message has been forwarded.

Dear Jeannine,

Please see the attached an electronic copy of the report. Thank you for proceeding with the review of our request on the registration amendments.

Regards,

Yong

Yong Gao, Ph.D.|Regulatory Affairs Manager
U.S. Regulatory Affairs Team|Monsanto Company
St Louis, Missouri 63167, USA|yong.gao@monsanto.com
314 694-2943 (o)|314 488-0971 (m)|314 694-3080 (fax)

-----Original Message-----
From: Kausch.Jeannine@epamail.epa.gov [mailto:Kausch.Jeannine@epamail.epa.gov]
Sent: Friday, July 11, 2008 1:51 PM
To: GAO, YONG [AG/1000]
Subject: EPA Reg. Nos. 524-575 and 524-576 - Request for electronic courtesy copy of study

Mr. Gao:

I have been assigned as the regulatory action leader responsible for processing the amendments submitted by Monsanto Company in relation to EPA Reg. Nos. 524-575 (MON 89034) and 524-576 (MON 89034 x MON 88017). The reviewer has requested an electronic copy of the following study:

Head, G.P. 2008. Assessment of the impact of MON 89034 introduction on Bt resistance development in European and Southwestern corn borer. Monsanto Company report number MSL0021297.

Would you please submit a electronic courtesy copy to me at your earliest convenience?

Thanks for your attention to this matter,

Jeannine Kausch

Environmental Protection Specialist
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
(703) 347-8920 (telephone)
(703) 305-0118 (fax)

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Gail
'Tomimatsu/DC/USEPA/US
07/10/2008 03:40 PM

To Teresa Downs/DC/USEPA/US@EPA

cc Jeannine Kausch/DC/USEPA/US@EPA, Alan Reynolds/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA

bcc

Subject Missing submission from Monsanto...per Alan Reynolds' phone call

Hello Theresa,

I have assumed the Team Leader Responsibilities from Alan Reynolds for the next 60 days or so. He just informed me that he discussed the missing Monsanto package with you via telephone; and I am sending confirming information (blue text below), as well. Also, since he will be out of the office for the next few days or so, you can call me tomorrow (Friday), if you happen to unearth the paper copy, and i can retrieve it from you at that time.

By the way, thanks for the "save" on the pending package from Becker-Underwood. I admit I returned it to the incorrect "done" shelf. We're still working on it.

Thanks again for your help, Teresa.

The data package was included with a submission from Monsanto Company (EPA Reg. No. 524-575; It also goes along with EPA Reg. No. 524-576 but a hard copy was not submitted with that application.). The pin-punch date on the submission is June 11, 2008.

best regards,
gail

Gail S. Tomimatsu, Ph.D.
Plant Pathologist & Acting Team Leader
Microbial Pesticides Branch
(703)-308-8543; FAXs: (703)-308-7026, 305-0118

Mailing Address:
U.S. EPA-OPP
Biopesticides and Pollution Prevention Division Mailcode: 7511P
1200 Pennsylvania Avenue, NW
Washington DC 20460

Courier Address:
U.S. EPA-OPP
Biopesticides and Pollution Prevention Division
8th Floor, S-8956
2777 Crystal Drive
Arlington, VA 22202

Jeannine Kausch/DC/USEPA/US
07/10/2008 03:19 PM

To Gail Tomimatsu/DC/USEPA/US@EPA
cc Sheryl Reilly/DC/USEPA/US@EPA
bcc
Subject Missing data package (#524-575, #524-576)

Hi Gail,

Below, please find the information requested for the missing data package:

Head, G.P. 2008. Assessment of the impact of MON 89034 introduction on Bt resistance development in European and Southwestern corn borer. Monsanto Company report number MSL0021297.

The data package was included with a submission from Monsanto Company (EPA Reg. No. 524-575; It also goes along with EPA Reg. No. 524-576 but a hard copy was not submitted with that application.). The pin-punch date on the submission is June 11, 2008.

Please let me know if you need any additional information. I appreciate the time you have taken to look into this!

Thanks,

Jeannine

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 16, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-394798
EPA File Symbol or Registration Number: 524-LTL
Product Name: MON 89034
EPA Receipt Date: 11-Jun-2008
EPA Company Number: 524
Company Name: MONSANTO COMPANY

RUSSELL P. SCHNEIDER
MONSANTO CO
MONSANTO COMPANY
1300 I STREET, NW, SUITE 450 EAST
WASHINGTON, DC 20005

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B900

AMENDMENT;PIP;NON-FAST-TRACK (EXCEPT B89 ABOVE);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

Sincerely,

Teresa Downs

Front End Processing Staff
Information Technology & Resources Management Division

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Fee for Service

{8309725~

This package includes the following

- ○ New Registration
- ◉ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ◉ BPPD
- ○ RD

Risk Mgr. 92

Receipt No. S-	830972
EPA File Symbol/Reg. No.	524-LTL
Pin-Punch Date:	6/11/2008

☐ This item is NOT subject to FFS action.

Action Code:

Requested: B900

Granted: B900

Amount Due: $ pd 10,500

Parent/Child Decisions:

☒ Inert Cleared for Intended Use ☒ Uncleared Inert in Product

Reviewer: S Reilly Date: 6/13/08

Remarks:

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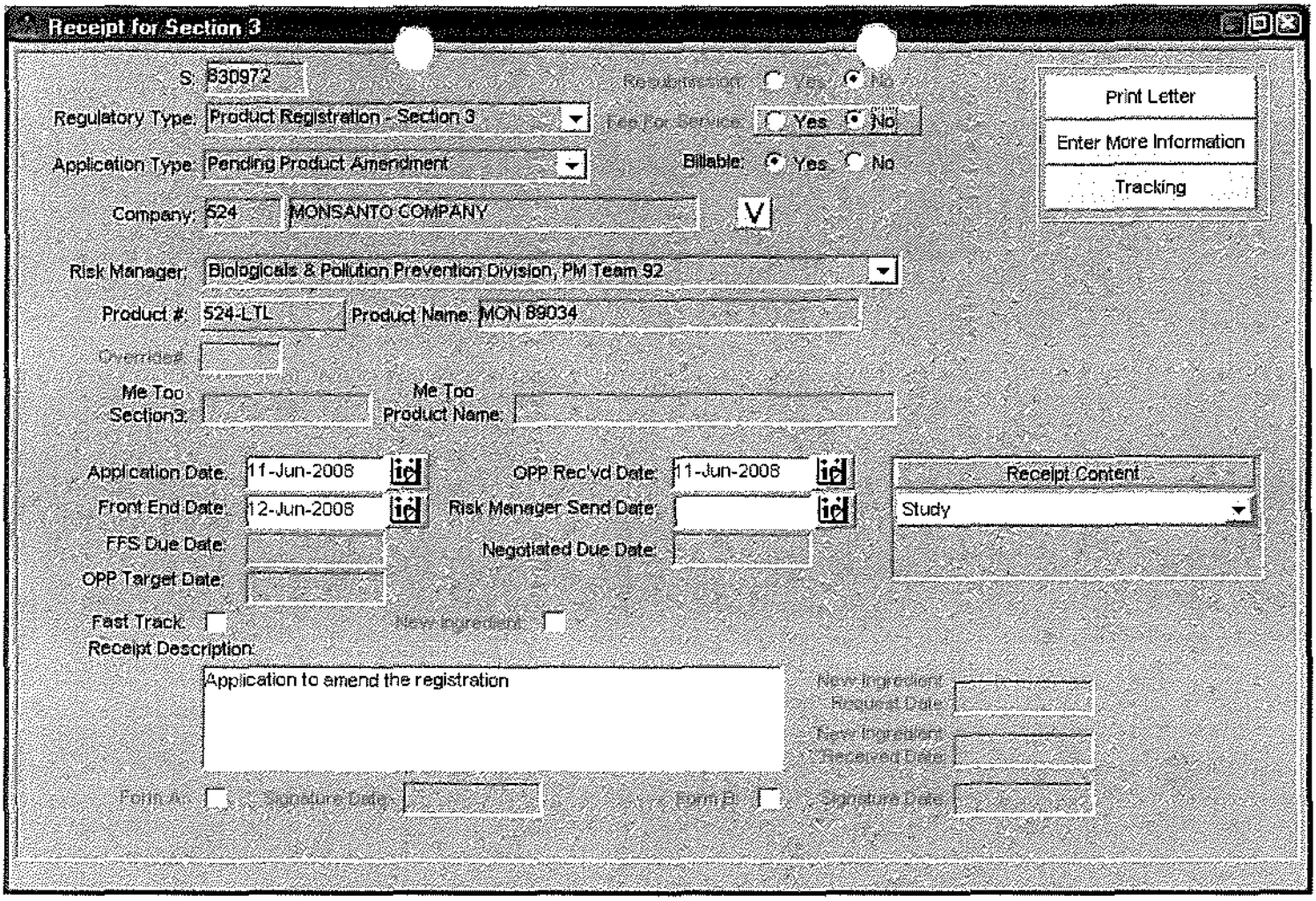
Receipt for Section 3
S: 830972
Regulatory Type: Product Registration - Section 3
Application Type: Pending Product Amendment
Company: 524 MONSANTO COMPANY
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 92
Product #: 524-LTL
Product Name: MON 89034
Me Too Section3:
Me Too Product Name:
Billable: Yes No
Print Letter
Enter More Information
Tracking
Application Date: 11-Jun-2008
Front End Date: 12-Jun-2008
FFS Due Date:
OPP Target Date:
OPP Rec'vd Date: 11-Jun-2008
Risk Manager Send Date:
Negotiated Due Date:
Receipt Content
Study
Fast Track:
Receipt Description:
Application to amend the registration

FEE FOR SERVICE

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: JUN 11 2008	EPA Reg. Number: 524-LTL

	Check List Item	Yes	No	N/A
1	Has the **PRIA Fee been Paid**; is a copy of the check or Pay.gov receipt included in the Submission Package?	X		
2	Is an **Application Form** (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	X		
3	Is a **Confidential Statement of Formula** (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	X		
4	Is a **Formulator's Exemption Statement** (EPA Form 8570-27) Included in the Submission Package?		X	
5	Is a **Certification with Respect to Citation of Data** (EPA Form 8570-34) Included in the Submission Package?	X		
6	Is a **Data Matrix** (EPA Form 8570-35) Included in the Submission Package?	X		
7	Is a **Label** Included in the Submission Package?	X		
8	Are **Data** Included in the Submission Package?	X		
9	**Is the Submission an Amendment?**	X		

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Sales or Other Commercial/Financial Information Is Not Included

Monsanto Company

NON NEGOTIABLE

1801229867

Accounts Payable Inquiries 314-694-2099, 800 N. Lindbergh, St. Louis, MO 63167

05/28/2008

Vendor Number: 371010

Invoice Number	Date	Gross Amount	Discount/Withld	Net Amt	Comments
LAIR050808	05/08/2008	10,500.00	0.00	10,500.00	EPA Registration No. 524-575 MON89034
Sum Total		10,500.00	0.00	10,500.00	

REMITTANCE ADVICE: The attached check is in full payment of invoices or other charges listed.

CHECK HAS A GREEN BACKGROUND, WATERMARK, MICROPRINT ON BACK, DO NOT CASH IF ALL ARE NOT PRESENT

MONSANTO

Monsanto Company
Accounts Payable Inquiries 314-694-2099
800 North Lindbergh, Saint Louis, MO 63167

62-20/311

1801229867

DATE 05/28/2008

VOID IF NOT CASHED WITHIN SIX MONTHS

PAY TO THE ORDER OF
ENVIRONMENTAL PROTECTION AGENCY
HQ ACCOUNTING OPERATIONS BRANCH
PM-226
PO Box 360399M
PITTSBURGH PA 15251-6399

********10,500.00*

THIS AMOUNT *TEN THOUSAND FIVE HUNDRED********** USD

PAYABLE AT
CITIBANK, N.A.
ONE PENNS WAY
19720 NEW CASTLE, DE 19720

by Terrell K. Green

by

Authorized Signatures

⑈1801229867⑈

[redacted]

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EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
File Symbol 524-575	Sheryl Reilly	☒ None ☐ Restricted
Company/Product (Name) MON 89034	PM # 90	

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167
☐ Check if this is a new address

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section – II

☒ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification – Explain below.
☐ Final printed labels in response to Agency letter dated
☐ "Me Too" Application.
☐ Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Administrative Materials for the Application to Amend the Registration of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034.

Section – III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No		☐ Yes ☐ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other
***Certification must be submitted**	*If "Yes" Unit Packaging wgt.*	No. per Container	*If "Yes" Package wgt.*	No. per Container	*(Specify)*

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section – IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. *(Include Area Code)*
Russell P. Schneider	Sr. Director, Regulatory Affairs & Policy	(202) 383-2866

Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title	4. Typed Name	5. Date
Yong Gao	Regulatory Affairs Manager	Yong Gao, Ph.D. Tel. (314) 694-2943	June 11, 2008

Please read instructions on reverse before completing form.
EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.
Form Approved. OMB No. 2070-0060. Approval Expires 2-28-95
White - EPA File Copy (original) Yellow - Applicant Copy

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EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S. W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC; 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant'sfRegistrant's Name, Address, and Telephone Number:	EPA Registration Number / File Symbol:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 (314)-694-2943	524-575
Active Ingredient(s) and/or representative test compound(s): *Bacillus thuringiensis* Cry tA.105 and Cry2Ab2 proteins and the genetic material (vector PV-ZMIR245) necessary for their production in MON 89034.	Date: June 11, 2008
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part t58: Terrestrial field crop	Product Name: MON 89034

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY

☐ [Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (t) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false of misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature	Date	Typed or Printed Name and Title
Yong Gao	June 11, 2008	Yong Gao, Ph.D. Regulatory Affairs Manager

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imagine

MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST LOUIS, MISSOURI 63167
http://www.monsanto.com

June 11, 2008

Dr. Sheryl Reilly, Chief
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: Application to amend the registration of MON 89034, EPA Registration No. 524-575

Dear Dr. Reilly:

On June 10, 2008, EPA granted Monsanto Company a conditional registration (EPA Reg No. 524-575) for MON 89034 insect protection corn with an expiration date of September 30, 2010. The registration requires that growers set aside 20% of their corn acres as a structured refuge for corn borers. Monsanto herein requests to amend the registration of MON 89034 to allow for 5% structured refuge in the Corn Belt (non-cotton growing regions) for corn borers.

MON 89034 produces two different *Bacillus thuringiensis* (Bt) proteins, Cry1A.105 and Cry2Ab2, both of which are highly efficacious against lepidopteran insect pests. The two proteins have important differences in their modes of action, which were discussed in the original registration request (Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn MON 89034. MRID 469514-30). In view of the dual effective dose and the distinct mode of action of the two proteins, the likelihood of resistance evolution is significantly reduced compared to single Bt protein-containing products. Therefore, MON 89034 is expected to be sustainable using a reduced structured refuge. In the petition to EPA for registration filed in September 2006,

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Monsanto requested to reduce structured refuge for corn borers in the U.S. Corn Belt to 5% for MON 89034 compared to the 20% for existing single Bt protein corn such as MON 810. Monsanto also requested to reduce structured refuge for corn borers in the southern cotton-growing regions to 20% for MON 89034 compared to 50% for single Bt protein-containing corn.

EPA granted a 20% structured refuge requirement for MON 89034 in the southern cotton-growing regions in the registration, EPA Reg No. 524-575. In a letter to Monsanto dated December 19, 2007, EPA indicated that they would require additional data to support MON 89034 field corn uses in the Corn Belt with a 5% structured refuge, specifically data on dose determination, cross resistance potential among Cry1A.105, Cry1F and Cry1Ac, and additional simulation modeling. Monsanto has generated additional data which consistently support the conclusion of the original petition submitted to EPA in September 2006.

In the current submission, cross-resistance potential among Cry1A.105, Cry2Ab2, and Cry1F was determined, and further deterministic modeling was conducted with various parameter settings that reflect both realistic scenarios, as well as unrealistic worst-cases. The following conservative assumptions were made in the modeling: (1) no natural refuge (alternative hosts) for European corn borer (ECB) or Southwestern corn borer (SWCB) is present, even though both species are known to use a variety of wild hosts that are common in corn agro-ecosystems; (2) resistance to Cry1A.105 and Cry2Ab2 is complete with no fitness costs, despite widespread evidence that Bt resistance generally is not complete and is accompanied by fitness costs; (3) the initial frequency of all resistance alleles is 0.005, which is as high as has been recorded for Bt resistant allele frequencies; (4) the Cry2Ab2 toxin and all Cry1 toxins (Cry1A.105, Cry1Ab, Cry1F) are 99.9% effective against ECB; (5) the Cry1 toxins are 99-99.5% effective against SWCB; and the Cry2Ab2 toxin is 85-95% effective against SWCB; (6) cross resistance among Cry1A.105, Cry1Ab, and Cry1F was modeled using three highly conservative scenarios: full cross-resistance only between Cry1Ab and Cry1F; full cross-resistance only between Cry1A.105 and Cry1F; or full cross-resistance among all three of these toxins; (7) heterozygote-resistant pests have twice the survivorship of fully susceptible individuals; (8) both ECB and SWCB have two generations on corn per year; and (9) market scenarios range from 100% MON 89034 to no MON 89034 adoption.

The results showed that for ECB, the resistant allele frequency for Cry2Ab2 was unchanged after 30 years with a 5% refuge under either adoption scenario (100% adoption of MON 89034 or a shared marketplace with single Bt products) and all cross-resistance scenarios. Similarly, the resistant allele frequency for Cry1A.105 was either unchanged or only slightly increased after 30 years under all scenarios, except when full cross-resistance was assumed among all of the Cry1 proteins. Even in this extremely unrealistic worst-case scenario, resistance to Cry1A.105 took 29 years to evolve. In contrast, complete resistance to the single gene products evolved in less than 30 years under both adoption scenarios even with a 20% refuge requirement.

With SWCB, under the cross-resistance base-case, the durability of the proteins in MON 89034 was greater than that of the proteins in the single Bt products under all efficacy and adoption scenarios, even though the refuge was 5% for MON 89034 compared with 20% for the single Bt products in all cases. The uniformity of this result across all assumptions of product adoption and the level of control provided by the proteins in MON 89034 shows the value of dual effective dose products like MON 89034 for IRM. When the marketplace was shared (adoption scenario 2), MON 89034 always had greater than 30 years of durability, while the single Bt products lasted from 17-23 years.

Even under the highly unrealistic worst-case cross-resistance scenario, resistance to Cry2Ab did not evolve in the 30 year period and resistance to the Cry1 proteins (which were all assumed to be cross-resistant) evolved in 17-29 years. Under the still highly conservative assumption of complete cross-resistance between Cry1A.105 and Cry1F (alternate base-case), resistance to Cry1A.105 only evolved in one case, and there took 28.5 years to develop. Therefore, assuming full cross-resistance among Cry1A.105 and the other Cry1 proteins present in the marketplace still resulted in little resistance development to the dual effective dose product MON 89034, even with the 5% refuge requirement for MON 89034 and 20% requirement for single protein products. In all cases modeled, the efficacy of Cry2Ab2 remained intact and the presence of MON 89034 extended the durability of the single protein products.

In summary, under all adoption, cross-resistance, and efficacy scenarios, deployment of MON 89034 with a refuge size of 5% was more durable than single trait products with 20% refuge and, in the more realistic scenarios, the pyramid was many times more effective than the single Bt products in delaying resistance in both ECB and SWCB.

In support of this application for an amendment, Monsanto is submitting the following:

- Transmittal Document

- Volume 1 of 2: Gao, Y. 2008. Administrative materials for the application to amend the registration of the plant-incorporated protectant *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 proteins and the genetic material (vector PV-ZMIR245) necessary for their production in MON 89034. This volume includes the following:
    a. Application for Pesticide Amendment (EPA Form 8570-1)*
    b. Certification with Respect to Citation of Data (EPA Form 8570-34) *
    c. Data Matrix (EPA Form 8570-35)**
    d. Product Label *
    e. Confidential Statement of Formula (CSF)***

- Volume 2 of 2: Head, G. P. 2008. Assessment of the impact of MON 89034 introduction on Bt resistance development in European and Southwestern corn borer. Monsanto Company report number MSL0021297.***

Note on confidentiality classification:
* Category A: Non-confidential and can be released to public

** Category B: Subject to the provisions of FIFRA Section 10(g) and therefore protected from disclosure to multinational or foreign pesticide producers. Redacted data matrix is non-confidential and can be released to public.

*** Category C: Confidential business information that is protected from any disclosure indefinitely by provision of FIFRA Section 10.

On June 2, 2005 the Federal Register published a notice from the EPA regarding fees and decision times for pesticides registrations [FR 70(105): 32327-32335]. Based on the "Pesticide Registration Improvement Renewal Act – PRIA II Fee Table – Effective October 1, 2007" published by EPA, this proposed amendment request to the registration of MON 89034 belongs to category B900 – Amendment (e.g., new IRM requirements that are applicant initiated; or amending a conditional registration to extend the registration expiration date with additional data submitted). The fee for category B900 is $10,500. Monsanto will wire this amount to EPA through electronic transfer.

If you have any questions with respect to this amendment request, please feel free to contact Dr. Russell Schneider, Senior Director, Monsanto Regulatory Affairs and Policy at (202) 383-2866, or me at the phone number or e-mail listed below. Thank you for your attention.

Sincerely,

Yong Gao

Yong Gao, Ph.D.
Regulatory Affairs Manager
(314) 694-2943 (office)
yong.gao@monsanto.com

cc: Russell Schneider, Monsanto
Carolyn Carrera, Monsanto

Plant-Incorporated Protectant Label

MON 89034 ← old brand name (YieldGard VT PRO™ corn)

Lepidopteran-Protected Corn
(OECD Unique Identifier: MON-89Ø34-3)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn.....0.002-0.0056%

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn.....0.0015-0.0055%

Percentage (wt/wt) on a dry weight basis whole plant (forage)

Caution

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS_____

EPA Registration No. 524-575

EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the Technology Use Guide.

MON 89034 can be used to protect corn plants from leaf, stalk, and ear damage caused by corn borers.

MON 89034 can be crossed with events MON 88017, TC1507, or DAS-59122-7 to produce combined trait corn products.

In order to minimize the risk of these pests developing resistance to MON 89034 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn and small scale research trials for observation, nor to commercial hybrid sweet corn.

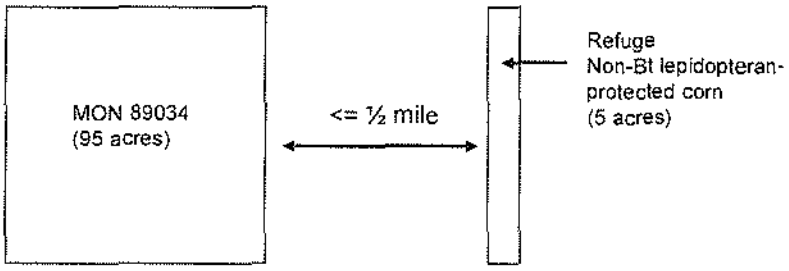
a) Corn-Belt/Non-Cotton Growing Areas

For MON 89034 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, discing, or plow-down within one (1) month of harvest.

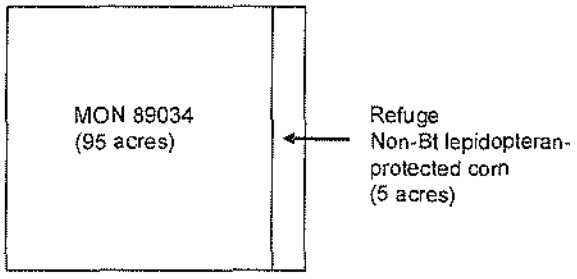
For MON 89034 field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower guides must specify that growers must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 5% corn which is not a lepidopteran-protected Bt corn hybrid. Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products.

Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.

External refuges must be planted within ½ mile.



When planting the refuge in strips across the field, refuges must be at least 4 rows wide.



Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, southern cornstalk borer, sugarcane borer, fall armyworm and corn stalk borer

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may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial Bt insecticides must not be applied to non-Bt corn refuges.

b) Cotton-Growing Area Refuge Requirements

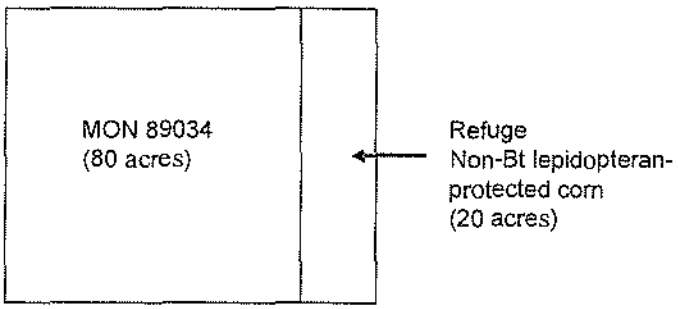
Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

For MON 89034 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, discing, or plow-down within one (1) month of harvest.

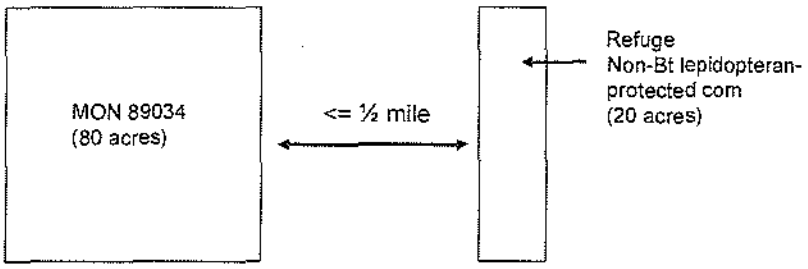
For lepidopteran-protected Bt field corn grown in cotton-growing areas, grower guides must specify that growers must adhere to the following refuge requirements.

Growers must plant a structured refuge of at least 20% corn which is not a lepidopteran-protected Bt corn hybrid. The refuge may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.

Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.



External refuges must be planted within ½ mile (1/4 mile or closer preferred).



When planting the refuge in strips across the field, refuges must be at least 4 rows wide.

Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, southern cornstalk borer, sugarcane borer, fall armyworm and corn stalk borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial Bt insecticides must not be applied to non-Bt corn refuges.

Corn Insects Controlled

European corn borer	*Ostrinia nubilalis*
Southwestern corn borer	*Diatraea grandiosella*
Southern cornstalk borer	*Diatraea crambidoides*
Corn earworm	*Helicoverpa zea*
Fall armyworm	*Spodoptera frugiperda*
Corn stalk borer	*Papaipema nebris*
Sugarcane borer	*Diatraea saccharalis*

Sales of corn hybrids that contain Monsanto's Bt corn plant incorporated protectant must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 6018100, 6051753, 6331665, 6489542, 6645497, 6962705, 7064249, and 7250501.

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Application to amend the registration for corn MON 89034
(OECD Unique Identifier: MON-89Ø34-3)

EPA Reg. No. 524-575

TRANSMITTAL DATE

June 11, 2008

MONSANTO REFERENCE No.

06-CR-172E-4

LIST OF SUBMITTED DOCUMENTS

Volume 1 of 2: Gao, Y. 2008. Administrative materials for the application to amend the registration of the plant-incorporated protectant *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 proteins and the genetic material (vector PV-ZMIR245) necessary for their production in MON 89034.

MRID Number _____

Volume 2 of 2: Head, G. P. 2008. Assessment of the impact of MON 89034 introduction on Bt resistance development in European and Southwestern corn borer. Monsanto Company report number MSL0021297.

MRID Number _____

Company Official: Yong Gao 6/11/2008

Yong Gao, Ph.D. Date
Regulatory Affairs Manager
Monsanto Company, St Louis, Missouri

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Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

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DATA MATRIX

Date: June 11, 2008	EPA Reg. No./File Symbol: 524-575	Page 1 of 12
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034	

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					

Signature	Name and Title	Date
	Yong Gao, Ph.D. Regulatory Affairs Manager	June 11, 2008

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. Agency Internal Use Copy

(121)

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: June 11, 2008	EPA Reg. No./File Symbol: 524-575	Page 12 of 12
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034	

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					

Signature	Name and Title Yong Gao, Ph.D. Regulatory Affairs Manager	Date June 11, 2008

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(17)

EPA Registration File No. 524-575 (Vol. 2).

Page _____ is not included in this copy.

Pages 192 through 193 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

__X__ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.

_____ Enforcement sensitive information.

_____ Attorney-Client Privilege.

____ Claimed Confidential by submitter upon submission to the Agency.

____ Internal Deliberative Information.

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* The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Form Approved OMB No. 2070-0060

EPA **UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
401 M Street, S.W.
Washington, D.C. 20460

DATA MATRIX

Date: June 11, 2008 | EPA Reg. No./File Symbol: 524-575 | Page 1 of 12

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier MON-89Ø34-3).		Monsanto Company	OWN	
885.1100	Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins Produced in Corn MON 89034	469514-01	Monsanto Company	OWN	Product Characterization
885.1100	Rice, J.F., B.J. Wolff, J.R. Groat, N.K. Scanlon, J.C. Jennings, and J.D. Masucci. 2006. Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034. Monsanto Technical Report MSL-20311.	469514-02	Monsanto Company	OWN	Product Characterization
885.1100	Hartmann, A.J., K.E. Niemeyer, and A. Silvanovich. 2006. Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL-20285.	469514-03	Monsanto Company	OWN	Product Characterization
885.1100	Karunanandaa, K., J.J. Thorp, M.E. Goley, S.L. Levine, and A. Silvanovich. 2006. Characterization of the Cry2Ab2 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and *E. coli*-Produced Cry2Ab2 Proteins. Monsanto Technical Report MSL-20071.	469514-04	Monsanto Company	OWN	Product Characterization

Signature	Name and Title	Date
	Yong Gao, Ph.D. Regulatory Affairs Manager	June 11, 2008

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Date: June 11, 2008	EPA Reg. No./File Symbol: 524-575	Page 2 of 12
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034	

Ingredient: *Bacillus thuringtensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Levine, S.L. and J. Uffman. 2006. Evaluation of the Functional Equivalence of the Cry2Ab2 Protein Produced in *E.Coli* and *Bt* Against a Sensitive Lepidopteran Species. Monsanto Technical Report MSL-20132.	469514-05	Monsanto Company	OWN	Product Characterization
885.1100	Rice, J.F , B.J. Wolff, J.C. Jennings, and f D. Masucci. 2005. Summary of Southern Blot Analysis of MON 89034 and MON 89597 Corn. Monsanto Technical Report MSL-20068	466945-01	Monsanto Company	OWN	Product Characterization
885.1100	Goertz, B., T. Ganguly, J. Lee, T. Lee, and E.A. Rice. 2005. Characterization of the Cry1A.105 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and *E.coli*-Produced Cry1A.105 Proteins. Monsanto Technical Report MSL-19960.	466946-04	Monsanto Company	OWN	Product Characterization
	Supplemental Information for MRID No 46951402 "Amended Report for MSL-20072: Molecular analysis of Corn MON 89034".	471275-03	Monsanto Company	OWN	Product Characterization
	Supplemental Information for MRID No. 46951403 "Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials".	471275-05	Monsanto Company	OWN	Product Characterization

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DATA MATRIX

Date: June 11, 2008	EPA Reg. No./File Symbol: 524-575	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034	

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Bogdanova, N.N. 2005. Structural and Functional Similarity of the Cry1A.105 Protein to Cry1A Class of *Bacillus thuringiensis* Proteins. Monsanto Technical Report 05-RA-62-01.	466946-01	Monsanto Company	OWN	Product Characterization
860.1340	Dudin, Y.A and P. Chinnadurai. 2005. Qualitative Detection Method for the Cry2Ab2 Protein in Corn Leaf and Seed of MON 89034 and MON 89597. Monsanto Technical Report 05-RA-39-04.	466945-03	Monsanto Company	OWN	Product Characterization
885.3050	Bonnette, K.L. 2006. An acute oral toxicity study in mice with Cry2Ab2 protein. Monsanto Study CRO-2005-049.	469514-06	Monsanto Company	OWN	Human Health Assessment
885.1100	Kapadia, S.A. and E.A. Rice. 2006. Assessment of the *in vitro* Digestibility of the Cry2Ab2 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19931.	469514-07	Monsanto Company	OWN	Human Health Assessment
885.1100	Kapadia, S. and E.A. Rice. 2005. Assessment of the *in vitro* Digestibility of the Cry1A.105 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19930.	469514-08	Monsanto Company	OWN	Human Health Assessment
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Ingredient: *Bacillus thuringiensis* Cry1A.105 and Cry2Ah2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	McCoy, R.L. and A. Silvanovich. 2005. Bioinformatics Analysis of the Cry1A.105 Protein Utilizing the AD5, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-19686.	466946-05	Monsanto Company	OWN	Human Health Assessment
885.1100	Thorp, J.J. and M.E. Goley. 2006. Assessment of the *in vitro* Digestibility of the Cry2Ab2 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19938	469514-09	Monsanto Company	OWN	Human Health Assessment
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Evaluation of the Cry1A.105 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Repon MSL-20351.	469514-10	Monsanto Company	OWN	Human Health Assessment
885.1100	Kapadia, S.A. and E.A. Rice. 2005. Assessment of the *in vitro* Digestibility of the Cry1A.105 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19929.	466946-06	Monsanto Company	OWN	Human Health Assessment
885.1100	Goley, M.E. and J.J. Thorp. 2005. Immunodetection of Cry2Ab2 and Cry1A.105 Proteins in Corn Grain from MON 89034 Following Heat Treatment. Monsanto Technical Report MSL-19899.	466946-07	Monsanto Company	OWN	Human Health Assessment
885.3050	Bonnette, K.L. 2005. An Acute Oral Toxicity Study in Mice with Cry1A.105 Protein. Monsanto Study CRO-2005-050.	466946-03	Monsanto Company	OWN	Human Health Assessment

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Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885 1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Analysis of the Cry2Ab2 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20307.	469514-11	Monsanto Company	OWN	Human Health Assessment
885 4050	Davis, S.W. 2006. Comparison of Broiler Performance and Carcass Parameters When Fed Diets Containing MON 89034, Control or Commercial Corn. Monsanto Study 05-01-50-13, Amended Report.	469514-12	Monsanto Company	OWN	Human Health Assessment
N/A	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of *Bacillus thuringiensis* Cry1A.105 Protein. Monsanto Technical Report MSL-20230.	469514-13	Monsanto Company	OWN	Environmental Assessment
N/A	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of *Bacillus thuringiensis* Cry2Ab2 Protein. Monsanto Technical Report MSL-20229.	469514-14	Monsanto Company	OWN	Environmental Assessment
N/A	Headrick, J.M., O. Heredia, I.O. Oyediran, and T.T. Vaughn. 2006. Assessment of the Efficacy of Lepidopteran-protected Corn MON 89034 and MON 89597 Against Major Insect Pests in United States, Puerto Rico and Argentina During 2003-2004 Seasons. Monsanto Technical Report 05-RA-39-05.	469514-15	Monsanto Company	OWN	Environmental Assessment

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Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Teixeira, D. 2006. Evaluation of Dietary Effects of Lyophilized Leaf Tissue from Corn MON 89034 in a Chronic Exposure Study with Collembola (*Folsomia candida*). Monsanto Technical Report MSL-20169.	469514-16	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S.J. and H.O. Krueger. 2006. Evaluation of Exposure to MON 89034 with the Cladoceran *Daphnia magna*: An acute static-renewal test with corn pollen. Monsanto Study WL-2005-011.	469514-17	Monsanto Company	OWN	Environmental Assessment
885.6200	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-20147.	469514-18	Monsanto Company	OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Honeybee Larvae (*Apis mellifera* L.). Monsanto Study CA-2005-071.	469514-19	Monsanto Company	OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Adult Honeybees (*Apis mellifera* L.). Monsanto Study CA-2005-072	469514-20	Monsanto Company	OWN	Environmental Assessment

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Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on the Ladybird Beetle, *Coleamegilla maculata* (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20150.	469514-21	Monsanto Company	OWN	Environmental Assessment
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on the Ladybird Beetle, *Coleomegilla maculata* (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20151.	469514-22	Monsanto Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on Minute Pirate Bugs, *Orius insidiosus* (Hemiptera: Anthocoridae). Monsanto Technical Report MSL-20170.	469514-23	Monsanto Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on Minute Pirate Bugs, *Orius insidiosus* (Hemiptera: Anthocoridae). Monsanto Technical Report MSL-20171.	469514-24	Monsanto Company	OWN	Environmental Assessment
885.4340	Sindenmann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Parasitic Wasp, *Ichneumon promissorius* (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20149.	469514-25	Monsanto Company	OWN	Environmental Assessment

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Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4050	Gallagher, S.P. and J.B. Beavers. 2006. Evaluation of Potential Dietary Effects of MON 89034 with the Northern Bobwhite: an Eight-day Dietary Study with Corn Grain. Monsanto Technical Report WL-2005-012.	469514-27	Monsanto Company	OWN	Environmental Assessment
885.5200	Mueth, M., T. Curran, J. Warren, S. Dubelman, M. Glaspie, J. Murphy, S. Levine, J. Holtmeyer, and C. Jiang. 2006. Aerobic Soil Degradation of the Purified Cry2Ab2 and Cry1A.105 Proteins. Monsanto Technical Report MSL-20174.	469514-28	Monsanto Company	OWN	Environmental Assessment
N/A	Huesing, J.E., J.J. Duan, and S.L. Levine. 2006. Endangered Species Risk Assessment for Corn MON 89034. Monsanto Technical Report MSL0020394.	469514-29	Monsanto Company	OWN	Environmental Assessment
N/A	MacRae, T.C., C.R. Brown, S.L. Levine. 2005. Evaluation of the Potential for Interactions Between the *Bacillus Thuringiensis* Proteins Cry1A.105 and Cry2Ab2. Monsanto Technical Report MSL-19859.	466946-02	Monsanto Company	OWN	Environmental Assessment
885.4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry2Ab2 Protein in an Acute Study with the Parasitic Wasp, *Ichneumon promissorius* (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20148.	469514-26	Monsanto Company	OWN	Environmental Assessment

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Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Palmer, S.J. and H.O. Krueger. 2000. Insect Protection Protein 2: An Acute Toxicity Study With the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-16177.	450863-13	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of dietary effect(s) of purified *Bacillus thuringiensis* Cry2Ab2 protein on honey bee larvae. Monsanto Technical Report MSL-16961.	453371-02	Monsanto Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2000. Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to Collembola (*Folsomia candida*), Amended report. Monsanto Technical Report MSL-16174.	450863-14	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. and H. Krueger. 2000. Insect Protection Protein 2: A Dietary Toxicity Study with Parasitic Hymenoptera (*Nasonia vitripennis*). Monsanto Technical Report MSL-16173.	450863-10	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Adult Honey Bees (*Apis mellifera* L.). Monsanto Technical Report MSL-16176.	450863-08	Monsanto Company	OWN	Environmental Assessment

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Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 | Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn, MON 89034. Monsanto Technical Report 06-RA-39-06.	469514-30	Monsanto Company	OWN	IRM
	Bogdanova, N. and A. Crawford (2007). Public Interest Document Supporting Registration of *Bacillus thuringiensis* Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins in Insect-Protected Corn MON 89034 and MON 89034 x MON 88017		Monsanto Company	OWN	Benefits
	Bogdanova, N., S. Dubelman, M. Mueth, J. Murphy and A. Silvanovich (2007). Responses to EPA Questions Regarding Application 524-575 to register Insect-Protected Corn MON 89034 (MRID 46951428)	471403-01	Monsanto Company	OWN	Misc.
	Bogdanova, N., (2007) Responses to EPA Questions Regarding Applications 524-575 and 524-575 to Register Insect-Protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	471275-01	Monsanto Company	OWN	Misc.
	Bogdanova, N., (2007). Supplemental Information to Address EPA Questions Regarding Applications 524-575 and 524-575 to Register Insect-Protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	470794-02	Monsanto Company	OWN	Misc.

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Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-31 152-34 152-35 885.3100	Not applicable since Cry1A.105 and Cry2Ab2 are plant incorporated protectants, are present at low levels, and there is little opportunity for dermal or ocular contact.				
152-32 885.3150	Not applicable since Cry1A.105 and Cry2Ab2 are plant incorporated protectants, are present at low levels, and there is little opportunity for human inhalation exposure. A pathogenicity determination is not applicable since Cry1.105 and Cry2Ab2 are not living organisms.				
152-33 885.3200	Not applicable since Cry1A.105 and Cry2Ab2 proteins are neither infective nor pathogenic.				
152-36 152-37 152-38 885.3400	There is no clear published evidence that has demonstrated clinical allergic reactions to Bt crystal proteins. Monitoring for hypersensitivity incidents can be implemented after registration is granted.				
152-39 885.3500	Not applicable since Cry1A.105 and Cry2Ab2 proteins are not living organisms				
154-17 885.4100	A pathogenicity determination is not applicable since Cry1A.105 and Cry2Ab2 are not living organisms.				
154-18 885-4150	Not applicable since there is no reason to suspect that wild mammals would be any more sensitive to Cry1A.105 and Cry2Ab2 than laboratory mammals. Mammals do not possess Cry protein receptors. A pathogenicity determination is not applicable since Cry1A.105 and Cry2Ab2 are not living organisms.				

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	Yong Gao, Ph.D. Regulatory Affairs Manager	June 11, 2008

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Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-21 885.4280	Results of acute toxicity tests with Daphnia did not produce any evidence of adverse effects. Testing with estuarine and marine species is not warranted because of very low to no potential for exposure to the Cry1A.105 and Cry2Ab2 proteins from field corn. A pathogenicity determination is not applicable since Cry1A.105 and Cry2Ab2 are not living organisms.				
154-22 885.4300	Cry1A.105 and Cry2Ab2 are insect toxins and Cry proteins have never been shown to cause toxicity in aquatic and terrestrial plants. The risk of outcrossing to weedy wild relatives is virtually nonexistent.				

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